STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH

Raul Pino, M.D., M.P.H.
Commissioner

Dannel P. Malloy
Governor

Nancy Wyman
Lt. Governor

Healthcare Quality And Safety Branch

December 18, 2018

Ms. Marna Borgstrom, Administrator
Yale-New Haven Hospital
20 York St
New Haven, CT 06504

Dear Ms. Borgstrom:

This is an amended edition of the violation letter originally dated November 29, 2018.

Unannounced visits were made to Yale-New Haven Hospital concluding on November 5, 2018 by representatives of the Facility Licensing and Investigations Section of the Department of Public Health for the purpose of conducting multiple investigations and a revisit for the purpose of review of the violation letter dated December 4, 2017.

Attached are the violations of the Regulations of Connecticut State Agencies and/or General Statutes of Connecticut which were noted during the course of the visits.

In accordance with Connecticut General Statutes, section 19a-496, upon a finding of noncompliance with such statutes or regulations, the Department shall issue a written notice of noncompliance to the institution. Not later than ten days after such institution receives a notice of noncompliance, the institution shall submit a plan of correction to the Department in response to the items of noncompliance identified in such notice.

The plan of correction is to be submitted to the Department by December 13, 2018.

The plan of correction shall include:

(1) The measures that the institution intends to implement or systemic changes that the institution intends to make to prevent a recurrence of each identified issue of noncompliance;

(2) the date each such corrective measure or change by the institution is effective;

(3) the institution's plan to monitor its quality assessment and performance improvement functions to ensure that the corrective measure or systemic change is sustained; and

(4) the title of the institution's staff member that is responsible for ensuring the institution's compliance with its plan of correction.

The plan of correction shall be deemed to be the institution's representation of compliance with the identified state statutes or regulations identified in the department's notice of noncompliance. Any institution that fails to submit a plan of correction may be subject to disciplinary action.

You may wish to dispute the violations and you may be provided with the opportunity to be heard. If the violations are not responded to by **December 13, 2018** or if a request for a meeting is not made by the stipulated date, the violations shall be deemed admitted.

DATES OF VISIT: July 10 11, August 20, October 2 and November 5, 2018

THE FOLLOWING VIOLATION(S) OF THE REGULATIONS OF CONNECTICUT STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES WERE IDENTIFIED

An office conference has been scheduled for **December 18, 2018 at 10:00 AM** in the Facility Licensing and Investigations Section of the Department of Public Health, 410 Capitol Avenue, Second Floor, Hartford, Connecticut to discuss those violations identified with an asterisk. Should you wish to retain legal representation, your attorney may accompany you to this meeting.

Alternate remedies to violations identified in this letter may be discussed at the office conference. In addition, please be advised that the preparation of a Plan of Correction and/or its acceptance by the Department of Public Health does not limit the Department in terms of other legal remedies, including but not limited to, the issuance of a Statement of Charges or a Summary Suspension Order and it does not preclude resolution of this matter by means of a Consent Order.

Should you have any questions, please do not hesitate to contact this office at (860) 509-7400.

Respectfully,

Susan H. Newton, R.N., B.S.
Supervising Nurse Consultant
Facility Licensing and Investigations Section

SHN:jf

Complaints: #23113, #22622, #22668, #23275 #22459 #23535, #23338, #23259, #22079, #22808, #22325, #22462, #22551, #23413, #22888, #23189, #23612, #22105, #22612, #22193, #22825, #21769, #22131, #22017, #23334, #21952, 22813, 21819, #22638, #22301, #22006, #23098, #23510, #21903, #22011, #22099, #22464, #22488, #22521, #23510, #24177, #24263 and #24262

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The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (d) Medical Records (2) and/or (e) Nursing Service (1) and/or (i) General (6).

1. *Based on clinical record review, policy review and interview the facility failed to ensure that for one of four patients reviewed that the patient's conservator was notified of the patient's condition and/or that a reassessment was documented and/or that a comprehensive discharge note was completed. The finding includes the following:
   a. Patient #70 presented to the ED on 10/2/18 at 1:08 PM for further management secondary to being obtunded after being sent from the PACU where the patient was scheduled for a battery change in his/her spinal stimulator. The patient had a history of polysubstance use, bipolar disorder and chronic back pain status post a spinal stimulator placement. The record indicated that the patient lives with his/her grandparents.

      The MD #58's note dated 10/2/18 at 2:41 PM indicated that the plan for the patient was sobriety hold secondary to his/her inability to remain awake, request a psychiatric clearance, labs and update the conservator when appropriate for discharge.

   b. Review of MD #59's note with the Director of ED on 11/5/18 at 12:30 PM indicated that MD #59's reevaluation indicated that the patient's condition had improved and that the disposition was discharged. The note failed to reflect a reassessment of the patient, the status of the psychiatric evaluation and/or that follow-up with the conservator had occurred. The ED Director indicated that he agreed that the note failed to reflect a comprehensive reassessment of the patient's condition and he was not comfortable with the omissions in the note. Review of the facility bylaws indicated that documentation must indicate that specific level of involvement of the consulting practitioner.

      Interview and chart review with the ED Safety Coordinator on 11/5/18 at 10:00 AM indicated that the chart indicated that the patient had conservator however review of the record failed to reflect the presence of the conservator documentation in the record. On investigation MD #59 indicated that she did not call the conservator identified in the record secondary to the lack of documentation. Interview with the ED director on 11/5/18 at 12:30 PM indicated that the facility expectation is that the provider attempts to call the conservator and confirm the status and document this in the record. Subsequent to this incident providers have been reeducated on the expectations.

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2. Based on clinical record review, interview and policy review the facility failed to ensure that for 3 of 4 patients receiving a blood product transfusion that the patients were monitored per the facility policy and/or that vital signs and/or an assessment completed when a transfusion reaction is suspected. The findings include the following:
   a. Patient #74 was admitted to the facility on 9/7/18 with for a stem cell transplant and a history of AML. Review of the clinical record indicated that on 10/4/18 the physician's orders directed that the patient receive 5 units of platelets. The record indicated that the platelets were administered at 2:20 PM and vital signs were obtained at that time. The next set of vital signs were obtained at 2:46 PM. The facility failed to ensure that vital signs were completed per policy.

      Review of Patient #74's nurse's note dated 10/4/18 at 5:00 PM indicated that the patent had started on 5 units of platelets when the nurse was called into the room secondary to the patient complaints of flank pain and rigors. The note indicated that Demerol and Benadryl were administered. The nursing documentation failed to reflect that vital signs had been obtained. Review of the transfusion reaction consult note indicated d that the platelets were stopped at 3:05 PM and the vital signs documented in the note were obtained at 2:46 PM and then at 4:03 PM, however a blood pressure was not obtained at that time. The vital signs were obtained next at 4:54 PM and indicated the patient's blood pressure was 66/34. Review of the policy indicated that if a transfusion reaction is suspected, in part, stop the transfusion, obtain/record vital signs, and document the patient's transfusion including symptoms, medications administered and other interventions.

   b. Patient #75 was presented to the outpatient infusion area on 10/4/18 for a platelet transfusion. The platelets were hung at 2:05 PM, the next set of vital signs were obtained at 2:31 PM and the patient had an increased pulse at that time. The note indicated that at 2:45 PM the patient experienced nausea, vomiting and diarrhea and the transfusion was discontinued at 3:05 PM. The facility failed to ensure that vital signs were completed per policy.

   c. Review of Patient #77's clinical record indicated that on 11/4/18 the physician directed that the patient receive one unit of packed red blood cells. The record indicated that the unit was hung at 10:31 AM at the same time the initial vital signs were obtained. The record indicated that the next set of vital signs were obtained at 10:57 AM. The facility failed to ensure that vital signs were completed per policy.

      Review of the facility policy indicated that the patient should be monitored for the first

fifteen minutes for signs of a transfusion reaction and document vital signs within the first 10-20 minutes from initiation of the infusion.

The following is a violation of the Regulation of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (e) Nursing Services (1) and/or (i) General (6).

3. Based on clinical record review, facility documentation and interviews for 2 of 3 sampled patients reviewed for fall risk, (Patient #33 and Patient #42) the facility failed to provide appropriate supervision and/or failed to ensure the bed alarm volume was operating efficiently when the patient exited the bed resulting in a serious injury and/or failed to accommodate the patient's needs while in restraints to prevent a fall. The findings include:
   a. Patient (PT) #33 was admitted on 4/22/17 status post MVC with multiple orthopedic and neurological injuries. Injuries included subdural hematoma, multiple cervical and lumbar spine fractures, pelvis fractures, left femur and forearm fractures.
   Review of the clinical record identified the patient had multiple falls. PT#33's plan of care identified he/she was at risk for falls, interventions were appropriate and were implemented. The clinical record identified on 5/11/17 PT#33 was in the recliner chair with chair alarm, nurse responded to chair alarm and found patient at foot of chair attempting to get up. The patient was assessed and identified to have a displaced C1 fracture. The patient was reassessed and the plan of care revised after the patient's fall on 5/11/17.

   The clinical record identified the patient was transferred to the step down unit on 5/30/17 for change in condition.

   Review of the fall assessment flow sheet for 5/31/17 identified the patient was assessed as a high fall risk (score 19). Interventions directed to keep bed in a low position, call bell within reach, bottom side rails down, keep area clutter free and utilize bed alarm.

   The nurse's note dated 5/31/17 at 7:45PM identified PT#33 was found on the floor lying in feces in his/her room. The note identified that PT#33 was last seen 30 minutes prior to the fall by RN# 23, bed was in low position, all four side rails up and bed alarm in place. PT#33 was also noted to be delirious prior to the fall. The note further identified a Posey vest and wrist restraints were discontinued earlier in the shift and replaced with bilateral mitts.

   The nurse's note dated 6/1/17 at 3:25AM identified PT#33 had a fall at the change of shift, patient assessment identified he/she was alert, confused to place and situation, neurovascular signs unchanged.

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Review of the clinical record failed to identify the patient was given an alternative method for a call bell i.e. tab call bell while bilateral mittens were in use. The patient was unable to call for assistance secondary to not being able to use a push button style call bell.

In an interview and clinical record review on 8/2/18 at 11:30 AM, the interim PSM #6 identified PT #33 had exhibited impulsive behavior, depression and anxiety when assessed at 9 AM on 5/31/17. PSM #6 identified the patient had bilateral mittens in place prior to the fall.

b. Patient (PT) #42 was admitted on 10/24/17 and underwent a scheduled aortic valve replacement (AVR) on 10/26/17.

PT #42's medical history included severe aortic stenosis, chronic obstructive pulmonary disease and morbid obesity.

Fall risk assessments dated 10/24/17 at 3:05 PM through 10/27/17 at 8:00 PM identified PT #42 as a high fall risk per clinical judgement.

The nurse's note dated10/26/17 identified PT #42 exhibited impulsive behaviors, disorientation and restlessness status post AVR procedure.

The nurse's note dated 10/27/17 at 11:09 AM identified radial arterial line and urethral catheter removed for patient safety secondary to impulsiveness and distraction behavior. An addendum note at 5:00 PM identified PT #42 with increasing restlessness and disoriented, interventions utilized not beneficial. After MD notification, Seroquel 25mg was administered and the note indicated will continue to monitor.

The nurse's note dated 10/28/17 at 4:02 AM identified PT #42 was observed on the floor by staff who had responded to a noise in the patient's room. The note identified an RN had observed the patient a few minutes prior and that the bed exit alarm had been activated but was not alarming. The note identified PT #42 reported he/she had attempted to exit the bed to void. The patient was assessed by an RN, evaluated by medical staff and assisted back to bed. The note further identified the patient complained of right hip pain.

The right hip CT scan dated 10/29/17 reported right intertrochanteric femur fracture.

Review of the clinic record identified PT#42 underwent a right hip intramedullary hip screw procedure on 10/29/17.

In an interview on 8/1/18 RN #17 identified on 10/28/17 he had checked on PT #42 during patient rounds which was completed approximately 3 AM. RN #17 identified that the patient

was restless, oriented to person which is his/her baseline and needed constant support. RN #17 further identified he was involved with another patient and that the PCA was attentive to the patient's requests. The patient had been incontinent of urine during the night and the bed was in a low position, side rails up, call bell and urinal within reach. RN #17 stated he knew that the bed alarm was on because the bed exit alarm feature light was on. RN #17 identified upon responding to a noise from PT#42's room he found the patient was on the floor and also identified the bed alarm was not sounding. After assessment of the patient and physician notification the patient was assisted back to bed.

In an interview on 8/1/18 at 2:20 PM, the Patient Service Manager (#5) identified review of the incident and checking of the bed determined that the bed alarm was on but the alarm sound could not be heard.

Review of the facility's Fall Prevention and Management policy identified in part high risk patients intervention to include activating bed alarm.

The following is a violation of the Regulation of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (c) Medical Staff (2) and/or (e) Nursing Services (1) and/or (l) Infection Control (1).

4. Based on clinical record review, facility documentation and interviews for 1 of 3 sampled patients (Patient #33) reviewed for surgical wounds, the facility failed to ensure that the site was assessed and/or failed to remove surgical staples according to the plan of care. The findings include:

    a. Patient (PT) #32 was admitted from home status post fall with diagnosis left hip fracture on 6/27/17. The intraoperative documentation dated 6/28/17 identified PT#32 underwent a left hip open reduction internal fixation (ORIF). Review of the incision assessment flow sheets from 6/28/17 thru 7/1/17 identified daily documentation for three separate areas on outer left thigh with dry and intact dressing. The discharge summary dated 7/1/17 identified staple removal to be addressed post discharge and to follow up in two weeks with orthopedic surgery. Review of the clinical record identified PT#32 was discharged to a facility for rehabilitation therapy on 7/1/17.

    The ED clinical record dated 7/6/17 identified PT#32 was readmitted to the facility for evaluation of altered mental status and agitation. The nursing admission note dated 7/6/17

identified incisions to left hip with staples and open to air.

The orthopedic consult note dated 7/10/17 identified assessment of left hip incision sites status post ORIF. The note further identified orthopedic surgeon (MD#38) aware of readmission, activity status to be weight bearing as tolerated with physical therapy and if patient remains in hospital for several more days to notify orthopedic services to remove staples before discharge.

The orthopedic note dated 7/13/17 identified APRN#2 responded to request for removal of staples. The progress note documentation identified initial surgery date (6/28/17), assessment of the surgical incision and removal of staples from the superior and inferior wound. The note also identified wound edges well approximated, mild serous drainage to superior incision, steri-strips and dry dressing applied.

The clinical record identified on 7/13/17 decision to opt for palliative care due to patient's inability to maintain hydration and nutrition and cognitive decline. PT#32 was discharged to Facility #1 on 7/14/17.

Review of Facility #1's history and physical admission note dated 7/14/17 identified assessment of left hip with three incisions; proximal incision with steri-strips, serosanguinous drainage and erythema, middle incision with erythema and two staples present in distal incision.

Review of the clinical record failed to identify documentation for retaining surgical staples post discharge and/or directions for care of the surgical site.

In an interview and clinical record review on 8/1/18 at 1:45 PM, APRN #2 identified she could not recall assessing and/or removing staples from PT #32's left hip. In addition APRN #2 indicated the orthopedic progress note dated 7/13/17 will reflect what was done when she assessed the patient.

Interview with MD #38 identified that the plan was for the staples to be removed in their entirety and he was not aware that the incision had two remaining staples when the patient was discharged.

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5. *Based on medical record reviews, for one of four patients (Patient #27) who had an order for MTP (massive blood transfusion protocol) and received multiple transfusions of RBC (red blood cells), the facility failed to ensure that hemodynamic status was adequately monitored during administration. The finding includes:

   a. Patient #27 was 23y/o, had an elective medication abortion on 1/17/2017 with recurrent persistent vaginal bleeding and was admitted to the ED on 6/7/17 following a syncopal episode with hypotension and continued vaginal bleeding. Point of care testing results dated 6/7/17 at 11:27 PM identified that the Patient's ionized calcium blood level was 4.10mg/dl (reference range: 4.48- 5.28). An order by MD #21 dated 6/8/17 at 1:08 AM directed MTP (massive transfusion protocol) due to the Patient's low blood pressure, hemodynamic instability and continued vaginal bleeding. Nursing documentation dated 6/8/17 and interview with Manager #5 on 7/27/18 noted that Patient #27 received a total of 13 units of RBC in the ED prior to going to IR (interventional radiology) at 3:17 AM on 6/8/17. MD #21 did not order that the Patient's calcium level be assessed and/or that calcium be administered during the time that the Patient received the PRBC in the ED.

      IR procedure documentation (uterine arteriogram and embolization) dated 6/8/17 indicated that, close to the conclusion of the procedure, the patient became bradycardic, hemodynamically unstable, pulseless, required CPR (cardiopulmonary resuscitation), was resuscitated, and was sent to the ICU (intensive care unit). The code resuscitation record and/or anesthesia record dated 6/8/17 identified that the Patient received calcium chloride at 5:23 AM and resuscitative efforts began at 5:43 AM. Point of care testing prior to the code and following the first calcium chloride administration noted that the Patient's ionized calcium level was 2.80 (low, low) at 5:30 AM and the Patient required 2 additional grams of calcium chloride during the code. The ICU admission history and physical dated 6/8/17 indicated that Patient #27 was status post cardiac arrest in the setting of likely hypocalcemia from massive transfusion.

      MD #21 was no longer employed by the Facility at the time of the investigation and was unavailable for interview. Interview with MD #13 on 7/26/18 at 1:17 PM identified that the Patient's calcium level seemed low and believed the possibilities of a low calcium level and cardiac collapse from continued bleeding played a role in the Patient's cardiac arrest. MD #13 further stated that blood contains the anticoagulant sodium citrate which binds with

calcium in the blood and therefore the patient would require additional calcium. MD #13 identified that the Attending Physician (MD #21) was responsible for ordering doses of calcium. Review of the MTP policy with MD #13 noted the policy lacked direction for calcium monitoring/administration during massive blood transfusions. Subsequent to the event, the facility developed a screen reminder in the EMR regarding calcium monitoring and administration during MTP.

The following is a violation of the Regulation of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (c) Medical Staff (2) and/or Connecticut General Statutes 19a-127n (b).

6. Based on medical record reviews, review of facility documentation, review of facility policies and interviews for one of seven patients who had an adverse event during hospitalization (Patient #23), the facility failed to ensure that the event was reported timely. The finding includes:

    a. Patient #23 was admitted for a liver transplant on 5/3/18. The operative report by MD #12 dated 5/3/18 identified an injury to the left phrenic vein extending to a tear in the left hepatic vein leading to air in the heart. The discharge summary dated 6/8/18 noted a defect in the inferior vena cava leading to a large air embolus identified during surgery during surgery and subsequent stroke per the head scan dated 5/5/18. The case review dated 5/11/18 indicated that the event occurred on 5/3/18 and the "Team" was notified of the event eight days later on 5/11/18. Facility documentation identified that the event was not reported timely to the State of Ct. DPH (department of public health), and the corrective action plan (CAP) was submitted on 6/15/18, 38 days following the event. Interview with RN #7 of the Transplant Quality and Safety on 7/26/18 at 11:00 AM noted that she was not aware that the event was an event that required state reporting until 6/12/18 and that is why the event was not reported timely. The facility policy for adverse event reporting identified a definition of a DPH reportable event included patient death or serious injury associated with intravascular air embolism that occurs while being cared for in a health care facility. The policy further identified that the Hospital had 7 days to write a report of the event and 30 days to submit a CAP to the DPH.

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7. Based on medical record reviews, review of facility policies and interviews for two of four patients who had a change in condition in the ED (Patient #9 and #7), the facility failed to ensure that physician notification of the change and/or a physician assessment of the change was documented. The findings include:

   a. Patient #9 was admitted to the ED on 8/11/17 at 12:29 PM for complaint of abdominal pain. Vital sign records dated 8/11/17 noted that the Patient's BP (blood pressure) was 120/82 (normal), pulse was 76 bpm (beats per minute- normal) and pain level was "7" (scale of 1-10) at 12:41PM. Vital signs dated 8/11/17 at 3:57 PM identified that the BP was 104/45 (low), pulse was 64 (slightly below normal) and pain level had increased to "9". Documentation that the LIP (licensed independent practitioner) had been notified of the changes in the Patient's BP and pain level had not been documented and the Patient was transported for a CT scan of the abdomen at 4:14 PM. During the scan, the patient became confused, had increased hypotension, a rupturing ileac artery was identified and the patient returned to the ED at 4:50 PM.

      Interview with Manager #5 on 7/31/18 at 10:50 AM noted that the PCT (patient care technician) documented that she notified RN #12 of the increased pain and abnormal BP at 3:57PM. Manager #5 indicated that this was a significant change for the Patient and believed that RN #5 notified the practitioner and had not documented the notification. Interview with MD #19 on 8/1/18 at 10:06 AM indicated that he would be more concerned if the patient was tachycardic with a low blood pressure and given that Patient's vital signs at 3:57 PM, he still would have sent the patient for the CT scan.

      The Facility RN job description identified an accountability to recognize changes in patient condition and report such changes to the Physician or Patient Services Manager. The job description lacked direction related to documentation responsibilities. The Facility nursing process and plan of care policy identified that a nursing progress note included documentation by exception and is utilized for significant changes.

   b. Patient #7 was admitted to the ED on 12/27/17 for LLE (Left lower extremity) swelling. An order by the LIP (licensed independent practitioner) dated 12/27/18 at 3:05 PM directed a urinalysis with culture reflex via straight catheterization. Nursing documentation and/or laboratory results did not reflect that the urinalysis or culture were performed. Physician documentation dated 12/27/18 by MD #23 indicated that Person #9 was upset, in part,

because there was some bleeding from the Patient's penis after a traumatic catheterization attempt that was never completed due to difficulty passing the catheter (very large prostate visualized on bladder volume ultrasound and aggressive behavior from the Patient). An assessment by MD #23 and/or the Resident, MD #24 was not documented. Review of the Patient's medical record and interview with Nurse Manager #5 on 7/31/18 at 11:35 AM noted that RN #11 did not document the attempted catheterization and should have documented this. Interview with RN #11 on 8/1/18 at 12:05 PM noted that she attempted to catheterize Patient #7 on 12/27/17, immediately pulled the catheter out when she felt resistance and there was a little bleeding. She further noted that she reported this to MD #23 and MD #24 and both went into the Patient's room after they were notified.

Interview with MD #16 on 8/2/18 at 1:59 PM identified that he was sure that MD #24 would have assessed the Patient, MD #24 had spent a lot of time with Patient #7 but, should have documented the assessment. MD #16 further indicated that he would discharge the Patient if the Patient had only slight urinary bleeding. A facility did not have a policy specific to required physician ED documentation.

The Facility nursing process and plan of care policy identified that a nursing progress note included documentation by exception and is utilized for significant changes.

The following is a violation of the Regulation of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (d) Medical Records (3).

8. Based on medical record reviews, review of facility documentation, review of facility policies and interviews for one of two patients who had medical records requested post discharge (Patient #9), the facility failed to ensure that all copies were sent as requested. The finding includes:

    a. Patient #9 was admitted to the ED on 8/11/17 at 12:29 PM for complaint of abdominal pain. The patient's ED record identified that the Patient was evaluated, in part, by MD #22, PA #2, APRN #1 and Resident #1. The authorization for medical record release by Person #10 sent to the facility on 8/23/17 indicated, in part, Patient #9's ED record, progress notes and history and physical from 7/23/18 to 8/12/18. Review of the medical records sent to Person #10 on 9/15/17 lacked copies of the entire ED record/visit dated 8/11/17. Interview with

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HIM (health information management) Staff #2 on 8/2/18 at 1:45 PM noted that certain documents in the ED record were entitled "consults" and were not sent to Person #10 as there was not a place on the request form to include this documentation request. HIM Staff #2 further indicated that the request form has since been revised in 2017 to include consult reports. The facility policy for release of protected health information identified only to release information upon the written authorization of patients or his/her Representative.

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9. Based on medical record reviews, review of facility policies and interviews for one of three patients (Patient #7) who were dependent for activities of daily living (ADL), the facility failed to ensure interventions were in place to address alterations in mobility. The finding includes:

Patient #7 was admitted to the ED on 12/28/17 for left lower leg swelling. The MD assessment dated 12/28/17 at 1:17 PM identified that the Patient had a right sided stroke in June 2017 with residual deficits and contracted lower extremity (left). Patient #7 was admitted to the in- patient unit on 12/28/17 for lower extremity swelling and hematuria. Admission orders dated 12/28/17 directed activity as tolerated. The orders did not include a PT (physical therapy) screen to address the contracted lower extremity. The initial nursing plan of care dated 12/28/17 failed to include the problem of impaired mobility and/or interventions. The wound care note dated 12/29/17 recommended to limit out of bed time to a maximum of one hour. Nursing documentation dated 12/30/17 for plan of care overview indicated that the Patient had contractures of bilateral lower extremities. MD progress notes dated 1/4/17 indicated that, prior to admission, Person #9 reported that the home aide was able to pivot the Patient to the chair and now the Patient seemed quite deconditioned and unable to do this. Physician orders dated 1/4/17 identified PT evaluation and treatment (7th hospital day). Physician orders dated 1/5/17 directed an x-ray of the left hip due to concern for hip dislocation. The PT assessment dated 1/5/17 noted pain in the left hip, holds hip strongly flexed and recommended PT 3x/week and daily ROM (range of motion). Review of the Patient's record from 12/28/17 to 1/11/17 with RN #10 on 8/2/18 at 11:22 AM identified that the Patient was transferred out of bed with the assistance of 2 staff on 12/2/17, 12/3/17, 12/5/17 and lacked any additional documentation for out of bed activity and/or documentation of patient activity refusals and/or staff performance of ROM. Interview with RN #10 on 8/2/18 indicated that although the Patient's plan of care included

pain interventions, the problem of mobility was not addressed by nursing. Although interview with the Rehab Manager (Manager #1) on 8/2/18 at 12:54 PM indicated that the Patient would receive ROM through repositioning, ROM to the upper and/or lower extremities was not documented by nursing. The facility policy for nursing process and plan of care identified that the plan of care is developed within 24 hours of admission and existing and identified problems, goals and interventions are evaluated once every 24 hours and updated as clinically relevant.

10. *Based on clinical record review, review of hospital documentation and interviews for 2 of 4 patients who had dental and/or surgical procedures (Patients #29 and #30) the hospital failed to ensure that the patient's did not sustain burns during the procedures. The findings include:

a. Patient #29 was admitted to the dental department on 10/20/17 for a root canal. During the procedure, the area was irrigated with sodium hypochlorite (sterilizing agent) which was standard practice. At the time of irrigation the patient complained of pain. It was identified that the tooth had been perforated during the reaming process and as a result, the sodium hypochlorite leaked through the perforation and came in contact with the patient's gum tissue causing a chemical burn. Interview with Dentist #1 (Program Director) on 7/10/18 at 2:15 PM identified that this is a known complication of a root canal procedure and that sodium hypochlorite contact with tissue is caustic. The patient experienced pain and face swelling and was referred to a specialist to complete the root canal. Subsequent to this incident, the concentration of the sodium hypochlorite was changed to decrease the caustic nature of the irregant.
b. Patient #30 was admitted on 4/3/17 with a diagnosis of hepatocellular carcinoma and underwent a laparoscopic liver ablation and biopsy. For the procedure an ablation device was used with two thermal grounding pads, one on each of the patient's inner thighs. Additionally, a Bair Hugger machine was used to cover and warm the patient per usual practice. During the procedure, the thermal grounding pad alarm alerted that the pads were overheating. At that time the Bair Hugger was turned to cooling mode and the remainder of the procedure was completed. Following the removal of the thermal grounding pads Patient #30 was noted with a 6cm x 4cm skin tear to the left inner thigh and a 10cm x 3 cm skin blister to the right inner thigh. Subsequent to the procedure, Patient #30 was diagnosed with a 3rd degree burn to the left thigh that included necrotic tissue with full thickness tissue loss in two areas requiring wound debridement. The 3rd degree burn was noted to be healed on 6/26/18.

Interview with MD #37 on 8/15/18 at 7:00 AM identified that he had performed hundreds of these procedures and this was the only case where a patient sustained a burn from the thermal grounding pad. MD #37 identified that all staff who were part of the surgical team had had

previous training in the use of the equipment. Subsequent to the incident, staff received additional education on the use of the equipment and that the Bair Hugger is to be placed below the grounding pads.

Interview with the Patient Safety Coordinator on 7/10/18 at 12:25 PM identified that when the thermal grounding pads alarmed the Bair Hugger was set on cool and the alarm stopped. When the grounding pads were removed following the procedure, the patient's left thigh was red and thought to have been a skin tear as the pads are very sticky and had skin tissue on it. Also, it is not uncommon for skin to be red when grounding pads are removed. Following this incident, all equipment was checked and no issues were identified. The likely cause of the burn was using the Bair Hugger over the grounding pads.

The following is a violation of the Regulation of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (c) Medical Staff (2) and/or (4) (A) and/or (d) Medical records (3) and/or (e) Nursing service (1) and/or (f) Diagnostic and therapeutic facilities and/or (i) General (6).

11. *Based on medical record review, review of facility policies, review of facility documentation and interviews for two of 16 patients reviewed for surgical services (Patient #57, #31), the facility failed to ensure that surgical instruments were not retained and/or staff were competent to remove a retained surgical instrument and/or ensure the safety of the patient intra-operatively and/or that the clinical record was accurate. The findings include:
    a. Patient #57 was admitted to the hospital on 3/14/18 with a 20 millimeter pelvic mass and scheduled for a robotic hysterectomy, bilateral salpingo-oopherectomy and resection of the pelvic mass. Review of the operative report dated 3/14/18 authored by MD #45 (Surgeon) indicated a RUMI uterine manipulator was placed in the cervix. The operative report and intraoperative documentation indicated all instrument and sponge counts were correct twice and MD #45 was present and scrubbed for the entire duration of the procedure.

    Review of RN #22's nurse's note dated 3/14/18 at 9:39 PM identified that the patient was received in the post anesthesia care unit (PACU) with stable vital signs, pain was relieved with fentanyl, intravenous (IV) Tylenol, and repositioning/knee elevation.

    Record review and interview with RN #22 on 8/20/18 at 2:55 PM stated that when she turned and repositioned the patient, she observed plastic tubing, approximately 6-8 inches in length protruding from the patient's genitalia, she called and spoke with Resident #3, who requested that she remove the occluder that was utilized during surgery. RN #22 stated she had never removed an occluder balloon (part of the uterine manipulator) before and had no formal training for such. Review of the record failed to reflect that RN #22 documented that the occluder balloon was retained, her conversation with Resident #3, the removal of the

occluder balloon and/or the patient's response to the removal of the retained surgical instrument.

Interview with Surgical Scrub Technician #1 on 9/6/18 at 10:45 AM stated on 3/14/18, she recalled completing the initial count prior to the start of the case with the Circulating Nurse (RN #24) and her routine is that she always counts the occluder balloon and would tell the nurse who documents this information. Surgical Scrub Technician #1 stated she gave report to Surgical Scrub Technician #2 at 4:20 PM then left the case.

Interview with Surgical Scrub Technician #2 on 8/31/18 at 12:10 PM stated when she entered the case on 3/14/18 at 4:20 PM, Resident #2 was in the process of doing the vaginal closure and that she did the final count with the Circulating Nurse (RN #24) who informed Resident #2 that counts were correct times two. Surgical Scrub Technician #2 stated the circulating nurse documents the counts and informs the surgeon of the count.

RN #24 was not available for interview.

During an interview on 9/6/18 at 8:25 AM, MD #45 indicated the RUMI uterine manipulator was placed by him in the beginning of the case. Once the surgery was completed, MD #45 stated MD #55 (Fellow) was in charge of the remainder of the surgery as he moved to his next case. MD #45 identified that he received a call that the occluder balloon was not removed before the patient left the operating room and removed by the PACU nurse post-operatively at the direction of Resident #3. MD #45 further stated that he thought the occluder balloon was part of the counts, however, was not, and that he expected this device to be removed intra-operatively.

Interview with Resident #2 on 9/24/18 at 3:30 PM identified that he should have removed the patient's Foley catheter and occluder balloon at the end of the case but was addressing a concern that the clamp that held the stirrup on the table came off causing the patient's leg to fall off the table.

Interview with the Operating Room Manager on 8/20/18 at 1:30 PM identified that during the period of time in which this event occurred (3/18), the OR staff were not counting vaginally inserted items. Subsequent to this event, the count worksheet was amended to include such instruments and all staff were educated.

Review of the Prevention of Retained Surgical Items (RSI) policy indicated instruments include all surgical tools or devices designed to perform a specific function. The policy indicated all counts after the initial count will start at the surgical field, move to the mayo stand, to the back table and off the field. The count sheet in the kit will be used to perform the initial instrument count. If there is no count sheet, total the instruments on the field and record the total on the count sheet/white board.

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The facility policy for prevention of retained surgical items identified that any item not identified as a sponge, sharp or instrument that are opened onto the sterile field are accounted for during all procedures. The policy further directed that counts must be done visually and audibly by the scrub person and RN circulator and in part, prior to wound closure.

b. Review of Patient #57's operative record dated 3/14/18 identified that the surgical procedure started at 3:38 PM and Scrub Technician #1 was present for the case from 2:32 PM through 4:47 PM. Review of the record identified that Scrub Technician and RN #24 performed the initial and first count. Interview with Surgical Technician #1 on 9/6/18 at 10:45 AM stated she recalled competing the initial count prior to the start of the case with the Circulating Nurse (RN #24) and was not present for the First closing count. Interview with the OR Manager on 9/6/18 at 11AM stated that the record was inaccurate in that RN #24 may have chosen the wrong Scrub Technician's name in the pull down section of the electronic medical record.

c. Review of Patient #57's operative report dated 3/14/18 identified that during mobilization of the patient from the operating room table to the stretcher, the stirrup that held the patient's leg in position during surgery, came unhinged. The patient did not appear to be injured, but an x-ray was taken and an orthopedic consult was called. Review of the pelvic x-ray report dated 3/14/18 identified no new fracture or dislocation was noted.

Review of facility documentation reflected that "upon completion of the case (3/14/18), the patient was in the lithotomy position, the right leg was repositioned for it was not positioned properly (lower than the left), the right leg fell with the stirrup still attached to it after the Resident let go after repositioning". Review of this incident with the OR Manager on 8/20/18 at 1:30 PM stated the stirrup was connected to the OR bed frame with a lug and subsequent to the incident, the lug was replaced. The Manager stated a work order was not requested. The hospital failed to ensure that human error was not ruled out as part of the investigation including but not limited to ensuring the patient's leg was properly placed in the stirrup and/or during position changes intra-operatively.

d. Patient #31 was admitted to the hospital on 6/15/17 with hypertensive urgency, shortness of breath, and chest pain. Review of the record identified that the patient had a cardiac catheterization on 5/20/17 which noted moderate to severe aortic valve stenosis. The patient was evaluated by MD#56 (cardiac surgeon) with a plan for aortic valve replacement on 6/22/17.

Review of the operative report dated 6/22/17 identified that two (2) atrial wires were placed and the patient was in sinus rhythm. A nurse's note dated 6/22/17 at 7:55 PM identified that the patient arrived to the intensive care unit, 100% AV paced at 80 bpm via epicardial wires, wires disconnected by PA, underlying normal sinus rhythm 60s-70s and wires reconnected

to pacemaker at backup rate of 45.DDD.

Review of the chest x-ray dated 6/23/17 noted interval placement of right apically terminating chest tube with resolution of right pneumothorax. Review of the clinical record dated 6/25/17 identified that the chest tube was removed at 12:10 PM.

Review of a nurse's note dated 6/26/17 at 2:40 AM noted that the patient's AV wires remain in place, surgical sites dry and intact, previous pleural chest tube dressing dry and intact. Review of the discharge nursing note dated 6/26/17 at 10:47 AM identified that the patient's epicardial wires were removed by the PA and the patient was discharged via wheel chair accompanied by RN. The record failed to note an assessment of the surgical sites by nursing staff prior to discharge.

Review of the discharge summary authored by PA #2 dated 6/26/17 at 11:09 AM indicated that the patient's right chest tube was removed on 6/26/17 with no residual pneumothorax on follow-up chest x-ray. The record failed to indicate that the atrial wire was removed prior to discharge and/or an assessment of the patient's surgical incisions.

Review of the clinical record with the Performance Improvement Manager and the Clinical Manager for cardiac/thoracic surgery, Physician Assistant (PA) #1 on 8/10/18 at 10:20 AM stated the record failed to indicate that PA #2 documented the removal of the pacer wires before discharge on 6/26/17 and during a post-operative visit on 6/30/17, MD #56 removed the temporary atrial pacing wire and one chest tube stitch.

Interview with MD #56 on 8/20/18 at 2:20 PM stated the atrial pacer wire should have been removed prior to discharge and believed it was overlooked because the patient had a dressing in place secondary to bleeding from the chest tube site.
PA #2 was unavailable for interview.

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12. Based on clinical record review and interview for 2 (P#5, P#8) of 4 patients reviewed for patients' rights the hospital failed to ensure the patients received high quality coordinated care and/or appropriate requested care and treatment. The findings include:

    a. Patient (P) #5, with a medical history of anxiety and amyotrophic lateral sclerosis (ALS)

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resulting in the inability to speak and eat resulting in a feeding tube for supplemental nutrition, presented to the Emergency Department (ED) on 12/6/17 at 8:47 AM from the outpatient neuromuscular clinic for a scheduled admission and elective tracheostomy placement on 12/7/17.

According to an admission History and Physical (H&P) the plan of care was to admit P#5 to the Neurology stepdown unit.

P #5 is evaluated by the Neurology Team at 9:54 AM and at 11:01 AM an order is written to admit P #5 to step down level of care. At 12:54 PM admission orders are entered and report is called from the ED to the unit at 1:26 PM however P#5 is not transferred to the unit until 12/7/17 at 12:49 AM (approximately 16 hours from arrival in ED). In addition at 12:54 PM an order is entered indicating that P #5 is to have nothing by mouth. P#5 is evaluated by nutrition services at 4:51 PM and the NPO order is verified at 5:57 PM and a tube feed diet is ordered at 6:04 PM and started (approximately 9 hours from arrival in ED).

Hospital documentation of the review of P#5's Grievance investigation identified Medical Doctor (MD) #3 indicated medical record review identified no call was made to the ED from the outpatient neurology clinic to arrange an admission on 12/6/17 causing a lack of communication between the Neurology team and the ED. ED care was reviewed and seemed reasonable although P#5 waited 16 hours for admission from the ED to a hospital unit. A neurology note asked that P#5 remain NPO pending the decision regarding the time of surgery on 12/7/17 however the decision to resume tube feedings was not made until approximately 7PM. MD#3 indicated he/she appreciated P#5's frustration.

During an interview with the Patient Grievance Coordinator on 7/24/18 at 12:27 PM he/she indicated in review of P#5's concerns areas for improvement were identified as clearer documentation and communication was need between Neurology and the ED staff to better understand the plan of care. In addition ED staff was provided additional education on caring for a patient with ALS and patients with deficits in communication.

b. P #8 was evaluated in the ED on 8/26/17 for evaluation of cholelithiasis. P #8 had diagnoses that included Diabetes Mellitus (DM) and was monitoring his/her blood sugar and administering insulin as needed at home.

A onetime blood sugar (BS) was ordered and checked on 8/26/17 at 6:14 PM in the ED with a result of 198 mg/dL (normal value 70-130 mg/dL). MD orders dated 8/27/17 indicated P#8 was to receive regular human Insulin every 6 hours on a sliding scale based on BS results.

A BS was ordered and checked at the request of P #8 in the ED on 8/27/17 at 1:00 AM with

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a result of 181 mg/dL. P #8 was admitted and underwent an MRI and was transferred to a patient care unit. Upon arriving on the patient care unit a BS was checked at 3:37 AM with a result of 171 mg/dL.

In review of the medical record the medical record lacked evidence blood sugars had been checked after on 8/27/17 from 3:37 AM until 5:46 PM at which time the result was 286 mg/dL. Subsequent to an evaluation by MD #1 P #8 received insulin and his/her blood sugar was monitored.

During an interview with the Manager of Patient Relations on 7/11/18 at 11:40 AM he/she indicated P #8 had expressed concern on 8/27/17 that he/she had made several inquiries during the day asking RN #2 to check his/her blood sugar. P #8 indicated he/she was upset and anxious at the time because he/she was concerned if his/her blood sugar was not controlled P #8 would develop complications such as loss of eyesight. P #8 indicated RN #2 indicated he/she could not check his/her blood sugar without a physician's order.

During an interview with RN #2 on 7/26/18 at 10:00 AM RN #3 did not recall the circumstances in caring for P#8 however he/she indicated if a patient asked for a blood sugar checks RN #2 would check for a physician's order. If there was no order he/she would call the MD and ask for an order.

During an interview with Assistant Patient Service Manager #1 on 7/24/18 at 2:00 PM he/she indicated the expectation would be if a DM patient came from the ED without BS monitoring orders the nurse should call the physician for orders. In this case RN #2 did not check P#8's blood sugar at P#8's request and/or call the physician for orders and he/she should have.

Hospital Patient Rights and Responsibilities Policy indicated the patient has the right to receive high quality coordinated care that is respectful and considerate and focused on the patient's individual needs. In addition the patient has the right to request care and treatment that is deemed medically necessary and appropriate within the hospitals capacity.

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The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (c) Medical Staff (4) and/or (d) Medical Records (2) and/or (e) Nursing Service (1), and/or (i) General (6).

13. Based on clinical record review, interview and policy review for 4 patients (Patients #24, #40, #43 and #44) the facility failed to ensure that the interdisciplinary treatment plan was reviewed, revised, updated and/or had input from all members of the ITP. The findings include the following:
    a. Review of Patient #24's clinical record indicated that the patient was admitted on 9/13/17 with a history of PTSD, depression presented with suicidal ideation. The physician note dated 9/26/17 indicated that Patient #24 disclosed to staff that he/she had been sexually touching another peer. The plan of care note dated 9/26/17 indicated that staff were informed by the physician that the patient alleged he/she engaged in inappropriate physical contact with roommate. The note indicated that the patient was placed in a single room and single seat within the milieu. Patient #24 was upset to be placed on single seat plan and was moved to a private room. Review of the interdisciplinary treatment plan (ITP) dated 9/21/17 failed to reflect that the ITP had been updated after the incident and/or prior to discharge on 10/19/18. Interview with RN # 16 on 7/25/18 at 9:00 AM indicated that the ITP should be updated every seven days or with a change of condition. Review of the policy indicated treatment is planned and delivered in an interdisciplinary and collaborative manner. The ITP is initiated within 24 hours and completed within 72 hours of admission by the treatment team, it is reflective of initial and ongoing biophysical assessment of the patients.

       In addition review of the ITP dated 9/21/17 failed to identify the names of the people involved in the creation of the ITP. The ITP listed the disciplines involved only. Interview with PSM # 3 on 7/25/18 at 9:30 AM indicated that there is a glitch in the computer system and that staff have to manually enter the names of staff involved. Interview with MD #33 on 8/1/18 at 10:00 AM indicated that the physician does not document on the ITP. MD #33 indicated that staff discuss issues at team meetings.

    b. Patient #40 admitted 9/20/17, the patient had a history of trauma, major depressive disorder and self-injurious behaviors being admitted for worsening depression with active suicidal ideation with a plan. Review of the treatment plan indicated that the patient's active problem was suicide ideation. Review of the physician's note dated 9/26/17 at 10:41 PM indicated that he met with the patient after hearing that he/she had sexual interaction with Patient #24. The note indicated that the patient was visibly shaken by the discussing this topic and appeared to have triggered from prior trauma. The note indicated that staff would plan to keep Patients #24 and 40 apart during groups, outside time and school. Review of the ITP dated 9/20/17 failed to reflect that the ITP was updated following this event and/or that the ITP was updated/revised prior to discharge on 9/28/17.

    c. Patient #43 was admitted on 7/19/18 with new onset psychosis. Review of the clinical record indicated that the ITP was completed on 7/20/18 and updated on 7/26/18 and 7/27/18 however

the ITP failed to reflect the involvement of the physician in the process, failing to make the plan interdisciplinary.

d. Patient #44 was admitted on 7/21/18 with homicidal ideation. Review of the record indicated that an ITP was completed on7/22/18 however the ITP failed to reflect the involvement of the physician in the process failing to make the plan interdisciplinary.

The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (d) Medical Records (2) and/or (e) Nursing Service (1), and/or (i) General (6).

14. Based on clinical record review, interview and policy review the facility failed to ensure that for 1 of 2 patients (Patient #38) that a safe discharge plan was in place. The findings include the following:
    a. Patient #38 presented to the ED via ambulance on 7/24/17 at 9:47 AM from a Skilled Nursing Facility (SNF). The patient complained of a large cyst under his/her breast, with complaints of an 8/10 pain. The note at 12:57 PM indicated that the patient was to be admitted. The physician note indicated that the patient had a 2 cm by 2 cm area under the right breast. The physician assistant note dated 7/24/17 at 11:42 M indicated that after the initial decision to admit the patient the patient became irritate because he/she was not receiving opioid pain medication. The patient indicated that he/she did not want to be admitted.
    The nurse's note dated 7/24/17 at 1:13 PM indicated that the patient was screaming at staff stating, "I just want you all to leave me alone, just get me discharged, I'm in pain, and you haven't even given me antibiotics yet". The note indicated that the patient refused a bedside US, lab and oral pain medication. The note dated 7/24/17 at 1:22 PM indicated that clindamycin and Ibuprofen were administered. Patient was given discharge instructions by RN. Patient screaming "I'll find my way out", not wanting to stay for vitals or provider instruction.

    The PA note dated 7/24/17 at 1:13 PM indicated that several hours after the patient had left the SNF called looking for the patient. The noted indicated that the PA, MD, ED Nurse Manager and RN discussed the case and reaffirmed that the patient had the mental capacity to make decisions.

    The ED admission dated 7/25/17 at 10:27 AM indicated that the patient returned to the ED. The note indicated that the patient had been seen the previous day and was discharged to the street instead of being sent to Leeway.

    Review of the facility policy related to Discharge Planning indicated that the physician/RN will

assess discharge disposition and coordinate travel if appropriate, facilitate preparation for a safe discharge and participate in information exchange with post discharge facility when appropriate. Review of the Patient Rights policy indicated that the patient has the right to receive high quality coordinated care that is respectful and considerate.

The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (d) Medical Records (2) and/or (e) Nursing Service (1), and/or (i) General (6)

15. Based on the clinical record review, interview and policy the facility failed to ensure that for 1 patient (Patient #39) the patient's level of pain was assessed and/or the patient's level of pain was addressed in a timely manner. The findings include the following:

a. Patient #39 presented on 7/5/17 to 11:58 AM for permcath removal, refusing to start dialysis because of pain and anxiety. The patient had complaints of chronic generalized pain, a 9 on a scale of 0-10 at 12:00 PM. The physician note indicated that the patient was to be admitted for pain management, electrolyte evaluation and a psychiatric evaluation. Review of the ED record with the ED Manager on 8/20/18 at 10:00 AM indicated that Oxycodone 1 tablet was administered at 3:36 PM. The record failed to reflect the rationale for not addressing the patient's level of pain initially. The record failed to reflect a pain reassessment prior to the administration of the medication. Review of Patient #39's clinical record indicated that at 4:37 PM the patient had a pain level of 9, however the record failed to reflect that the patient's pain level was addressed at that time.

Review of Patient #39's clinical record indicated that MD # 25 directed Oxycodone 10 mg every four hours for moderate pain (4-6). The clinical record indicated that on 7/5/17 at 5:00 PM the patient had a pain level of 10 that was not addressed. The record indicated that the patient received 10 mg of Oxycodone at approximately 7:00 PM, even though the stated pain level was outside the parameters ordered. The patient had a pain assessment of 10 at 11:07 PM and Oxycodone 10 mg was administered, the patient was reassessed for efficacy at 12:00 AM. The facility failed to ensure that the physician was notified of the patient's level of pain to comprehensively address the pain level of a 10.

Although review of the clinical record with the Nurse Manager on 8/20/18 at 10:15 AM indicated the patient received Oxycodone 10 mg on 7/6/17 at 5:21 AM, no further pain

assessments were completed after the 12:00 AM assessment on 7/6/17 through discharge at 4:24 PM on 7/6/17.

The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (a) Physical Plant (4) and/or (i) General (6).

16. Based on tour the facility failed to ensure that a private sanitary environment was available to all patients on the children's psychiatric unit. The findings include the following:
    a. Tour of the children's psychiatric unit on 8/1/18 at 9:15 AM identified that the privacy curtains were not present throughout the unit in the semiprivate patient rooms, not allowing patient privacy while changing and/or sleeping. Interview with staff indicated that the curtains were removed because patients would pull them down and the facility would have to put the curtains back in place.
    b. Tour of the children's psychiatric on 8/1/18 at 9:15 AM identified that the floor in the common area was discolored and peeling.

The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (d) Medical Records (2) and/or(e) Nursing Service (1) and/or (i) General (6).

17. Based on clinical record review, policy review and interview for 1 of 3 patients (Patient #4) the facility failed to ensure that CIWA monitoring was completed. The findings include the following:
    a. Patient #4 was admitted on 4/14/18 with a recent fall, depression, anxiety disorder, panic attacks and a history of benzodiazepine abuse on methadone. The H&P indicated that the patient stated that he/she obtained Xanax illicitly for depression.

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Review of the 4/15/17 Psychiatric consult indicated that the patient endorsed depression and positive suicidal ideation in the ED. Patient reporting taking 2 mg of Xanax daily. Review of the physician's orders dated 4/16/18 at 11:10 AM directed CIWA monitoring to be completed three times a day. Review of the clinical record by the Quality representative indicated that the CIWA monitoring was completed on 4/17/18 at 10:00 PM and 4/18/18 at 6:00 AM. The facility failed to ensure that the monitoring was completed as directed.

Approved
1/3/19
SHN

Yale NewHaven Health
Yale New Haven Hospital

January 3, 2019

Susan H. Newton RN, BS
Supervising Nurse Consultant
Facility Licensing and Investigations Sections
410 Capital Avenue
P.O. Box 340308
Hartford, CT 06134-0308

RE: Yale New Haven Hospital Letter of Violation, Amended December 18, 2018.

Dear Ms. Newton,

Attached is Yale New Haven Hospital's (YNHH) response to your amended letter dated December 18, 2018 containing plans of correction and response for the five additional violations set forth in the amended letter. Please confirm receipt of the corrective action plans back to Victoria Dahl Vickers.

If you need additional information, please contact Victoria at Victoria.Vickers@ynhh.org or by phone at (203) 688-6374.

Sincerely,

Michelle Y. Poynton
Accreditation & Regulatory Affairs Specialist
Clinic Building, 1st Floor, Room CB1049J
Yale New Haven Health
20 York Street
New Haven, CT 06510

MP: attachment

CC: Victoria Dahl Vickers

FACILITY: Yale-New Haven Hospital

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1. *Based on clinical record review, policy review and interview the facility failed to ensure that for one of four patients reviewed that the patient's conservator was notified of the patient's condition and/or that a reassessment was documented and/or that a comprehensive discharge note was completed. The finding includes the following:
   a. Patient #70 presented to the ED on 10/2/18 at 1:08 PM for further management secondary to being obtunded after being sent from the PACU where the patient was scheduled for a battery change in his/her spinal stimulator. The patient had a history of polysubstance use, bipolar disorder and chronic back pain status post a spinal stimulator placement. The record indicated that the patient lives with his/her grandparents.

      The MD #58's note dated 10/2/18 at 2:41 PM indicated that the plan for the patient was sobriety hold secondary to his/her inability to remain awake, request a psychiatric clearance, labs and update the conservator when appropriate for discharge.

   b. Review of MD #59's note with the Director of ED on 11/5/18 at 12:30 PM indicated that MD #59's reevaluation indicated that the patient's condition had improved and that the disposition was discharged. The note failed to reflect a reassessment of the patient, the status of the psychiatric evaluation and/or that follow-up with the conservator had occurred. The ED Director indicated that he agreed that the note failed to reflect a comprehensive reassessment of the patient's condition and he was not comfortable with the omissions in the note. Review of the facility bylaws indicated that documentation must indicate that specific level of involvement of the consulting practitioner.

      Interview and chart review with the ED Safety Coordinator on 11/5/18 at 10:00 AM indicated that the chart indicated that the patient had conservator however review of the record failed to reflect the presence of the conservator documentation in the record. On investigation MD #59 indicated that she did not call the conservator identified in the record secondary to the lack of documentation. Interview with the ED director on 11/5/18 at 12:30 PM indicated that the facility expectation is that the provider attempts to call the conservator and confirm the status and document this in the record. Subsequent to this incident providers have been reeducated on the expectations.

FACILITY: Yale-New Haven Hospital

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1a,b.	DPH Plan of Correction	Completion Date
•	Yale New Haven Hospital (YNHH) York Street Campus (YSC) Emergency Department (ED) Medical Director discussed YNHH's process when the Electronic Medical Record (EMR) does not have evidence of a court appointed Conservator of Person with ED faculty and residents at the faculty meeting.	November 9, 2018
•	YNHH YSC ED Clinical Manager of Advanced Practice Practitioners (APPs) discussed YNHH's process when the EMR does not have evidence of a court appointed Conservator of Person with ED APPs at the APP staff meeting.	November 9, 2018
•	YNHH YSC ED Medical Director discussed YNHH's documentation expectations with YSC ED faculty and residents at the faculty meeting.	December 7, 2018
•	YNHH Clinical Manager of APPs discussed YNHH's documentation expectations with YSC ED APPs at the APP staff meeting.	December 7, 2018
•	Monitoring Plan: o Ten medical records per month for three months in YNHH YSC ED will be reviewed for documentation of attempts to reach conservators. Beginning: December 17, 2018	March 15, 2019
•	The YSC ED Medical Director has been designated to oversee the monitoring of these corrective actions.	

The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (d) Medical Records (2) and/or (e) Nursing Service (1) and/or (i) General (6)

2. Based on clinical record review, interview and policy review the facility failed to ensure that for 3 of 4 patients receiving a blood product transfusion that the patients were monitored per the facility policy and/or that vital signs and/or an assessment completed when a transfusion reaction is suspected. The findings include the following:
   a. Patient #74 was admitted to the facility on 9/7/18 with for a stem cell transplant and a history of AML. Review of the clinical record indicated that on 10/4/18 the physician's orders directed that the patient receive 5 units of platelets. The record indicated that the platelets were administered at 2:20 PM and vital signs were obtained at that time. The next set of vital signs were obtained at 2:46 PM. The facility failed to ensure that vital signs were completed per policy.

      Review of Patient #74's nurse's note dated 10/4/18 at 5:00 PM indicated that the patent had started on 5 units of platelets when the nurse was called into the room secondary to the patient complaints of flank pain and rigors. The note indicated that Demerol and Benadryl were administered. The nursing documentation failed to reflect that vital signs had been

obtained. Review of the transfusion reaction consult note indicated d that the platelets were stopped at 3:05 PM and the vital signs documented in the note were obtained at 2:46 PM and then at 4:03 PM, however a blood pressure was not obtained at that time. The vital signs were obtained next at 4:54 PM and indicated the patient's blood pressure was 66/34. Review of the policy indicated that if a transfusion reaction is suspected, in part, stop the transfusion, obtain/record vital signs, and document the patient's transfusion including symptoms, medications administered and other interventions.

b. Patient #75 was presented to the outpatient infusion area on 10/4/18 for a platelet transfusion. The platelets were hung at 2:05 PM, the next set of vital signs were obtained at 2:31 PM and the patient had an increased pulse at that time. The note indicated that at 2:45 PM the patient experienced nausea, vomiting and diarrhea and the transfusion was discontinued at 3:05 PM. The facility failed to ensure that vital signs were completed per policy.

c. Review of Patient #77's clinical record indicated that on 11/4/18 the physician directed that the patient receive one unit of packed red blood cells. The record indicated that the unit was hung at 10:31 AM at the same time the initial vital signs were obtained. The record indicated that the next set of vital signs were obtained at 10:57 AM. The facility failed to ensure that vital signs were completed per policy. Review of the facility policy indicated that the patient should be monitored for the first fifteen minutes for signs of a transfusion reaction and document vital signs within the first 10-20 minutes from initiation of the infusion.

2a-c. DPH Plan of Correction	Completion Date
• The North Pavilion (NP) 7 Hematologic Oncology and NP 11 Inpatient Hematologic Oncology Registered Nurses will be re-educated to obtain and document vital signs on patients receiving blood products as per Yale New Haven Health System (YNHHS) policy titled "Blood Administration". • Monitoring Plan: o Five medical records per unit per week on NP 7 Hematologic Oncology and NP 11 Inpatient Hematologic Oncology will be audited for two months for documentation of vital signs on patient's receiving blood products. Beginning : February 1, 2019 • The Patient Services Managers of NP 7 Hematologic Oncology and NP 11 Inpatient Hematologic Oncology have been designated to oversee the monitoring of these corrective actions.	January 25, 2019 April 5, 2019

The following is a violation of the Regulation of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (e) Nursing Services (1) and/or (i) General (6).

3. Based on clinical record review, facility documentation and interviews for 2 of 3 sampled patients reviewed for fall risk, (Patient #33 and Patient #42) the facility failed to provide appropriate

supervision and/or failed to ensure the bed alarm volume was operating efficiently when the patient exited the bed resulting in a serious injury and/or failed to accommodate the patient's needs while in restraints to prevent a fall. The findings include:

a. Patient (PT) #33 was admitted on 4/22/17 status post MVC with multiple orthopedic and neurological injuries. Injuries included subdural hematoma, multiple cervical and lumbar spine fractures, pelvis fractures, left femur and forearm fractures.
Review of the clinical record identified the patient had multiple falls. PT#33's plan of care identified he/she was at risk for falls, interventions were appropriate and were implemented. The clinical record identified on 5/11/17 PT#33 was in the recliner chair with chair alarm, nurse responded to chair alarm and found patient at foot of chair attempting to get up. The patient was assessed and identified to have a displaced C1 fracture. The patient was reassessed and the plan of care revised after the patient's fall on 5/11/17.

The clinical record identified the patient was transferred to the step down unit on 5/30/17 for change in condition.

Review of the fall assessment flow sheet for 5/31/17 identified the patient was assessed as a high fall risk (score 19). Interventions directed to keep bed in a low position, call bell within reach, bottom side rails down, keep area clutter free and utilize bed alarm.

The nurse's note dated 5/31/17 at 7:45PM identified PT#33 was found on the floor lying in feces in his/her room. The note identified that PT#33 was last seen 30 minutes prior to the fall by RN# 23, bed was in low position, all four side rails up and bed alarm in place. PT#33 was also noted to be delirious prior to the fall. The note further identified a Posey vest and wrist restraints were discontinued earlier in the shift and replaced with bilateral mitts.

The nurse's note dated 6/1/17 at 3:25AM identified PT#33 had a fall at the change of shift, patient assessment identified he/she was alert, confused to place and situation, neurovascular signs unchanged.

Review of the clinical record failed to identify the patient was given an alternative method for a call bell i.e. tab call bell while bilateral mittens were in use. The patient was unable to call for assistance secondary to not being able to use a push button style call bell.

In an interview and clinical record review on 8/2/18 at 11:30 AM, the interim PSM #6 identified PT #33 had exhibited impulsive behavior, depression and anxiety when assessed at 9 AM on 5/31/17. PSM #6 identified the patient had bilateral mittens in place prior to the fall.

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3a. DPH Plan of Correction	Completion Date
• South Pavilion (SP) 6-4 clinical nurses and Patient Care Associates (PCAs) will be re-educated on alternative methods for a call bell when a patient has mitts on. • Monitoring Plan: o Ten clinical nurses or PCAs per month for two months on SP 6-4 will attend simulations regarding use of alternative methods for a call bell when a patient has mitts on. Beginning : February 4, 2019 • The Patient Services Manager of SP 6-4 has been designated to oversee the monitoring of these corrective actions.	January 25, 2019 March 29, 2019

b. Patient (PT) #42 was admitted on 10/24/17 and underwent a scheduled aortic valve replacement (AVR) on 10/26/17.

PT #42's medical history included severe aortic stenosis, chronic obstructive pulmonary disease and morbid obesity.

Fall risk assessments dated 10/24/17 at 3:05 PM through 10/27/17 at 8:00 PM identified PT #42 as a high fall risk per clinical judgement.

The nurse's note dated10/26/17 identified PT #42 exhibited impulsive behaviors, disorientation and restlessness status post AVR procedure.

The nurse's note dated 10/27/17 at 11:09 AM identified radial arterial line and urethral catheter removed for patient safety secondary to impulsiveness and distraction behavior. An addendum note at 5:00 PM identified PT #42 with increasing restlessness and disoriented, interventions utilized not beneficial. After MD notification, Seroquel 25mg was administered and the note indicated will continue to monitor.

The nurse's note dated 10/28/17 at 4:02 AM identified PT #42 was observed on the floor by staff who had responded to a noise in the patient's room. The note identified an RN had observed the patient a few minutes prior and that the bed exit alarm had been activated but was not alarming The note identified PT #42 reported he/she had attempted to exit the bed to void. The patient was assessed by an RN, evaluated by medical staff and assisted back to bed. The note further identified the patient complained of right hip pain.

The right hip CT scan dated 10/29/17 reported right intertrochanteric femur fracture.

Review of the clinic record identified PT#42 underwent a right hip intramedullary hip screw procedure on 10/29/17.

In an interview on 8/1/18 RN #17 identified on 10/28/17 he had checked on PT #42 during patient rounds which was completed approximately 3 AM. RN #17 identified that the patient

was restless, oriented to person which is his/her baseline and needed constant support. RN #17 further identified he was involved with another patient and that the PCA was attentive to the patient's requests. The patient had been incontinent of urine during the night and the bed was in a low position, side rails up, call bell and urinal within reach. RN #17 stated he knew that the bed alarm was on because the bed exit alarm feature light was on. RN #17 identified upon responding to a noise from PT#42's room he found the patient was on the floor and also identified the bed alarm was not sounding. After assessment of the patient and physician notification the patient was assisted back to bed.

In an interview on 8/1/18 at 2:20 PM, the Patient Service Manager (#5) identified review of the incident and checking of the bed determined that the bed alarm was on but the alarm sound could not be heard.

Review of the facility's Fall Prevention and Management policy identified in part high risk patients intervention to include activating bed alarm.

3b.	DPH Plan of Correction	Completion Date
•	The use of hook and loop belt and bed pad alarm and the circumstances in which to use the hook and loop belt was reviewed with RNs and Patient Care Associates in Cardiothoracic Intensive Care Unit (CTICU).	December 4, 2017
•	RNs in CTICU were educated to Stop, Think, Act and Review (STAR) prior to leaving a patient room to assess bed alarm light is on and volume is up and to ask themselves this question: Do I have concerns about this patient over-estimating their ability to mobilize or get out of bed (OOB) (stand, walk impulsiveness)?	December 4, 2017
•	Unit leadership observed 5 opportunities a week for 8 weeks of high risk fall patients and discussed with the nurses caring for the patients' needs for any additional strategies such as hook and loop belt, bed pad alarm, OOB to chair, rearrangement of bed/furniture or use of family when appropriate, with 100% compliance.	January 8, 2018
•	The Patient Service Manager Cardiothoracic Intensive Care Unit was designated to oversee the monitoring of these corrective actions.	

The following is a violation of the Regulation of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (c) Medical Staff (2) and/or (e) Nursing Services (1) and/or (I) Infection Control (1).

4. Based on clinical record review, facility documentation and interviews for 1 of 3 sampled patients (Patient #33) reviewed for surgical wounds, the facility failed to ensure that the site was assessed and/or failed to remove surgical staples according to the plan of care. The findings include:

   a. Patient (PT) #32 was admitted from home status post fall with diagnosis left hip fracture on 6/27/17. The intraoperative documentation dated 6/28/17 identified PT#32 underwent a left

hip open reduction internal fixation (ORIF). Review of the incision assessment flow sheets from 6/28/17 thru 7/1/17 identified daily documentation for three separate areas on outer left thigh with dry and intact dressing. The discharge summary dated 7/1/17 identified staple removal to be addressed post discharge and to follow up in two weeks with orthopedic surgery. Review of the clinical record identified PT#32 was discharged to a facility for rehabilitation therapy on 7/1/17.

The ED clinical record dated 7/6/17 identified PT#32 was readmitted to the facility for evaluation of altered mental status and agitation. The nursing admission note dated 7/6/17 identified incisions to left hip with staples and open to air.

The orthopedic consult note dated 7/10/17 identified assessment of left hip incision sites status post ORIF. The note further identified orthopedic surgeon (MD#38) aware of readmission, activity status to be weight bearing as tolerated with physical therapy and if patient remains in hospital for several more days to notify orthopedic services to remove staples before discharge.

The orthopedic note dated 7/13/17 identified APRN#2 responded to request for removal of staples. The progress note documentation identified initial surgery date (6/28/17), assessment of the surgical incision and removal of staples from the superior and inferior wound. The note also identified wound edges well approximated, mild serous drainage to superior incision, steri-strips and dry dressing applied.

The clinical record identified on 7/13/17 decision to opt for palliative care due to patient's inability to maintain hydration and nutrition and cognitive decline. PT#32 was discharged to Facility #1 on 7/14/17.

Review of Facility #1's history and physical admission note dated 7/14/17 identified assessment of left hip with three incisions; proximal incision with steri-strips, serosanguinous drainage and erythema, middle incision with erythema and two staples present in distal incision.

Review of the clinical record failed to identify documentation for retaining surgical staples post discharge and/or directions for care of the surgical site.

In an interview and clinical record review on 8/1/18 at 1:45 PM, APRN #2 identified she could not recall assessing and/or removing staples from PT #32's left hip. In addition APRN #2 indicated the orthopedic progress note dated 7/13/17 will reflect what was done when she assessed the patient.

Interview with MD #38 identified that the plan was for the staples to be removed in their entirety and he was not aware that the incision had two remaining staples when the patient was discharged.

4a.	DPH Plan of Correction	Completion Date
	• This event will be shared at the Center for Musculoskeletal Care Advanced Practice Provider (APP) staff meeting.	December 13, 2018
	• APPs in the Center for Musculoskeletal Care will be re-educated to include proper documentation of wound assessment, suture/staple removal, number of incisions and follow-up wound care in the note following suture/staple removal.	December 13, 2018
	• The Center for Musculoskeletal Care Clinical Manager has been designated to oversee the monitoring of these corrective actions.	

The following is a violation of the Regulation of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (c) Medical Staff (2) (i) General (6).

5. *Based on medical record reviews, for one of four patients (Patient #27) who had an order for MTP (massive blood transfusion protocol) and received multiple transfusions of RBC (red blood cells), the facility failed to ensure that hemodynamic status was adequately monitored during administration. The finding includes:

a. Patient #27 was 23y/o, had an elective medication abortion on 1/17/2017 with recurrent persistent vaginal bleeding and was admitted to the ED on 6/7/17 following a syncopal episode with hypotension and continued vaginal bleeding. Point of care testing results dated 6/7/17 at 11:27 PM identified that the Patient's ionized calcium blood level was 4.10mg/dl (reference range: 4.48- 5.28). An order by MD #21 dated 6/8/17 at 1:08 AM directed MTP (massive transfusion protocol) due to the Patient's low blood pressure, hemodynamic instability and continued vaginal bleeding. Nursing documentation dated 6/8/17 and interview with Manager #5 on 7/27/18 noted that Patient #27 received a total of 13 units of RBC in the ED prior to going to IR (interventional radiology) at 3:17 AM on 6/8/17. MD #21 did not order that the Patient's calcium level be assessed and/or that calcium be administered during the time that the Patient received the PRBC in the ED.

IR procedure documentation (uterine arteriogram and embolization) dated 6/8/17 indicated that, close to the conclusion of the procedure, the patient became bradycardic, hemodynamically unstable, pulseless, required CPR (cardiopulmonary resuscitation), was resuscitated, and was sent to the ICU (intensive care unit). The code resuscitation record and/or anesthesia record dated 6/8/17 identified that the Patient received calcium chloride at 5:23 AM and resuscitative efforts began at 5:43 AM. Point of care testing prior to the code and following the first calcium chloride administration noted that the Patient's ionized

calcium level was 2.80 (low, low) at 5:30 AM and the Patient required 2 additional grams of calcium chloride during the code. The ICU admission history and physical dated 6/8/17 indicated that Patient #27 was status post cardiac arrest in the setting of likely hypocalcemia from massive transfusion.

MD #21 was no longer employed by the Facility at the time of the investigation and was unavailable for interview. Interview with MD #13 on 7/26/18 at 1:17 PM identified that the Patient's calcium level seemed low and believed the possibilities of a low calcium level and cardiac collapse from continued bleeding played a role in the Patient's cardiac arrest. MD #13 further stated that blood contains the anticoagulant sodium citrate which binds with calcium in the blood and therefore the patient would require additional calcium. MD #13 identified that the Attending Physician (MD #21) was responsible for ordering doses of calcium. Review of the MTP policy with MD #13 noted the policy lacked direction for calcium monitoring/administration during massive blood transfusions. Subsequent to the event, the facility developed a screen reminder in the EMR regarding calcium monitoring and administration during MTP.

5a.	DPH Plan of Correction	Completion Date
	• The Massive Transfusion Protocol (MTP) order set was enhanced such that serum and ionized calcium are pre-selected to be drawn during the course of a massive transfusion. This will incorporate the calcium monitoring into the process and substantially reduce the risk of hypocalcemia-related hemodynamic instability. • The Executive Director of Clinical Operations was designated to oversee the monitoring of these corrective actions.	July 30, 2018

The following is a violation of the Regulation of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (c) Medical Staff (2) and/or Connecticut General Statutes 19a-127n (b).

6. Based on medical record reviews, review of facility documentation, review of facility policies and interviews for one of seven patients who had an adverse event during hospitalization (Patient #23), the facility failed to ensure that the event was reported timely. The finding includes:

   a. Patient #23 was admitted for a liver transplant on 5/3/18. The operative report by MD #12 dated 5/3/18 identified an injury to the left phrenic vein extending to a tear in the left hepatic vein leading to air in the heart. The discharge summary dated 6/8/18 noted a defect in the inferior vena cava leading to a large air embolus identified during surgery during surgery and subsequent stroke per the head scan dated 5/5/18. The case review dated 5/11/18 indicated that the event occurred on 5/3/18 and the "Team" was notified of the event eight days later on 5/11/18. Facility documentation identified that the event was not reported timely to the State of Ct. DPH (department of public health), and the corrective action plan (CAP) was submitted on 6/15/18, 38 days following the event. Interview with

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RN #7 of the Transplant Quality and Safety on 7/26/18 at 11:00 AM noted that she was not aware that the event was an event that required state reporting until 6/12/18 and that is why the event was not reported timely. The facility policy for adverse event reporting identified a definition of a DPH reportable event included patient death or serious injury associated with intravascular air embolism that occurs while being cared for in a health care facility. The policy further identified that the Hospital had 7 days to write a report of the event and 30 days to submit a CAP to the DPH.

6a.	DPH Plan of Correction	Completion Date
•	The Connecticut Department of Public Health (Ct. DPH) Adverse Event Reporting Categories and Timelines were reviewed at the monthly Liver & Kidney Quality Assurance Performance Improvement (QAPI) Multidisciplinary Team Meetings.	June 19, 2018
•	The expectations for timely DPH Adverse Event Reporting and a review of the Ct. DPH Adverse Event Reporting Categories was distributed to the Multidisciplinary Liver & Kidney Teams.	June 20, 2018
•	The case was reviewed and discussed at the monthly Transplant Quality Case Review Meeting of the known complication of air embolism associated with liver transplantation along with the DPH adverse event definitions and reporting timeframes.	July 30, 2018
•	Monitoring Plan: o Ten members of the Multidisciplinary Liver & Kidney Team will participate in a Teach Back audit to ensure understanding of the CT DPH Adverse Event Reporting Categories and Timelines of reporting. Beginning: December 20, 2018	February 1, 2019
•	The Transplant Quality and Patient Safety Coordinator has been designated to oversee the monitoring of these corrective actions.	

The following is a violation of the Regulation of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (c) Medical Staff (2) and/or (d) Medical records (3) and/or (e) Nursing Services (1) and/or (i) General (6).

7. Based on medical record reviews, review of facility policies and interviews for two of four patients who had a change in condition in the ED (Patient #9 and #7), the facility failed to ensure that physician notification of the change and/or a physician assessment of the change was documented. The findings include:

   a. Patient #9 was admitted to the ED on 8/11/17 at 12:29 PM for complaint of abdominal pain. Vital sign records dated 8/11/17 noted that the Patient's BP (blood pressure) was 120/82 (normal), pulse was 76 bpm (beats per minute- normal) and pain level was "7" (scale of 1-10) at 12:41PM. Vital signs dated 8/11/17 at 3:57 PM identified that the BP was 104/45 (low), pulse was 64 (slightly below normal) and pain level had increased to "9". Documentation that the LIP (licensed independent practitioner) had been notified of the

changes in the Patient's BP and pain level had not been documented and the Patient was transported for a CT scan of the abdomen at 4:14 PM. During the scan, the patient became confused, had increased hypotension, a rupturing ileac artery was identified and the patient returned to the ED at 4:50 PM.

Interview with Manager #5 on 7/31/18 at 10:50 AM noted that the PCT (patient care technician) documented that she notified RN #12 of the increased pain and abnormal BP at 3:57PM. Manager #5 indicated that this was a significant change for the Patient and believed that RN #5 notified the practitioner and had not documented the notification. Interview with MD #19 on 8/1/18 at 10:06 AM indicated that he would be more concerned if the patient was tachycardic with a low blood pressure and given that Patient's vital signs at 3:57 PM, he still would have sent the patient for the CT scan.

The Facility RN job description identified an accountability to recognize changes in patient condition and report such changes to the Physician or Patient Services Manager. The job description lacked direction related to documentation responsibilities. The Facility nursing process and plan of care policy identified that a nursing progress note included documentation by exception and is utilized for significant changes

b. Patient #7 was admitted to the ED on 12/27/17 for LLE (Left lower extremity) swelling. An order by the LIP (licensed independent practitioner) dated 12/27/18 at 3:05 PM directed a urinalysis with culture reflex via straight catheterization. Nursing documentation and/or laboratory results did not reflect that the urinalysis or culture were performed. Physician documentation dated 12/27/18 by MD #23 indicated that Person #9 was upset, in part, because there was some bleeding from the Patient's penis after a traumatic catheterization attempt that was never completed due to difficulty passing the catheter (very large prostate visualized on bladder volume ultrasound and aggressive behavior from the Patient). An assessment by MD #23 and/or the Resident, MD #24 was not documented. Review of the Patient's medical record and interview with Nurse Manager #5 on 7/31/18 at 11:35 AM noted that RN #11 did not document the attempted catheterization and should have documented this. Interview with RN #11 on 8/1/18 at 12:05 PM noted that she attempted to catheterize Patient #7 on 12/27/17, immediately pulled the catheter out when she felt resistance and there was a little bleeding. She further noted that she reported this to MD #23 and MD #24 and both went into the Patient's room after they were notified.

Interview with MD #16 on 8/2/18 at 1:59 PM identified that he was sure that MD #24 would have assessed the Patient, MD #24 had spent a lot of time with Patient #7 but, should have documented the assessment. MD #16 further indicated that he would discharge the Patient if the Patient had only slight urinary bleeding. A facility did not have a policy specific to required physician ED documentation.

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The Facility nursing process and plan of care policy identified that a nursing progress note included documentation by exception and is utilized for significant changes.

7 a,b.	DPH Plan of Correction	Completion Date
•	YNHH developed an Electronic Medical Record (EMR) Emergency Services documentation guideline that specifically includes changes in patient's condition with provider notifications, attempted nursing interventions with any related issues and reason for incomplete orders. The ED clinical registered nurses will be educated to the guideline.	January 4, 2019
•	Yale New Haven Hospital (YNHH) -York Street Campus (YSC) Emergency Department (ED) Medical Director discussed documentation expectations with YSC ED faculty and residents at the faculty meeting.	December 7, 2018
•	YNHH Clinical Manager of Advanced Practice Practitioners (APPs) discussed documentation expectations with YSC ED APPs at the APP staff meeting.	December 7, 2018
•	Monitoring Plan:	
	◦ Ten medical records per month for three months in YNHH ED will be reviewed for documentation of changes in patient's condition with provider notifications, attempted nursing interventions with any related issues and reason for incomplete orders. Beginning: January 7, 2019	April 5, 2019
	◦ Ten medical records per month for three months in YNHH YSC ED will be reviewed for documentation of disposition. Beginning: December 17, 2018	March 15, 2019
•	The Interim Nursing and Medical Director of YNHH Emergency Service Line have been designated to oversee the monitoring of the corrective actions.	

The following is a violation of the Regulation of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (d) Medical Records (3).

8. Based on medical record reviews, review of facility documentation, review of facility policies and interviews for one of two patients who had medical records requested post discharge (Patient #9), the facility failed to ensure that all copies were sent as requested. The finding includes:

a. Patient #9 was admitted to the ED on 8/11/17 at 12:29 PM for complaint of abdominal pain. The patient's ED record identified that the Patient was evaluated, in part, by MD #22, PA #2, APRN #1 and Resident #1. The authorization for medical record release by Person #10 sent to the facility on 8/23/17 indicated, in part, Patient #9's ED record, progress notes and history and

physical from 7/23/18 to 8/12/18. Review of the medical records sent to Person #10 on 9/15/17 lacked copies of the entire ED record/visit dated 8/11/17. Interview with HIM (health information management) Staff #2 on 8/2/18 at 1:45 PM noted that certain documents in the ED record were entitled "consults" and were not sent to Person #10 as there was not a place on the request form to include this documentation request. HIM Staff #2 further indicated that the request form has since been revised in 2017 to include consult reports. The facility policy for release of protected health information identified only to release information upon the written authorization of patients or his/her Representative.

8a.	DPH Plan of Correction	Completion Date
•	The YNHH Health Information Management document titled Authorization to Release/Disclose Protected Health Information was enhanced to include the ability to request consult reports and renamed as the Authorization for Access/Release of Information.	July 31, 2018
•	The Director of Hospital Information Management was designated to oversee the monitoring of these corrective actions.	

The following is a violation of the Regulation of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (c) Medical Staff (2) and/or (d) Medical records (3) and/or (e) Nursing Services (1) and/or (i) General (6).

9. Based on medical record reviews, review of facility policies and interviews for one of three patients (Patient #7) who were dependent for activities of daily living (ADL), the facility failed to ensure interventions were in place to address alterations in mobility. The finding includes:

Patient #7 was admitted to the ED on 12/28/17 for left lower leg swelling. The MD assessment dated 12/28/17 at 1:17 PM identified that the Patient had a right sided stroke in June 2017 with residual deficits and contracted lower extremity (left). Patient #7 was admitted to the in- patient unit on 12/28/17 for lower extremity swelling and hematuria. Admission orders dated 12/28/17 directed activity as tolerated. The orders did not include a PT (physical therapy) screen to address the contracted lower extremity. The initial nursing plan of care dated 12/28/17 failed to include the problem of impaired mobility and/or interventions. The wound care note dated 12/29/17 recommended to limit out of bed time to a maximum of one hour. Nursing documentation dated 12/30/17 for plan of care overview indicated that the Patient had contractures of bilateral lower extremities. MD progress notes dated 1/4/17 indicated that, prior to admission, Person #9 reported that the home aide was able to pivot the Patient to the chair and now the Patient seemed quite deconditioned and unable to do this. Physician orders dated 1/4/17 identified PT evaluation and treatment (7th hospital day). Physician orders dated 1/5/17 directed an x-ray of the left hip due to concern for hip dislocation. The PT assessment dated 1/5/17 noted pain in the left hip, holds hip strongly flexed and recommended PT 3x/week and daily ROM (range of motion). Review of the Patient's record from 12/28/17 to 1/11/17 with RN #10 on 8/2/18 at 11:22 AM identified that the Patient was transferred out of bed with the assistance of 2 staff on 12/2/17, 12/3/17,

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12/5/17 and lacked any additional documentation for out of bed activity and/or documentation of patient activity refusals and/or staff performance of ROM. Interview with RN #10 on 8/2/18 indicated that although the Patient's plan of care included pain interventions, the problem of mobility was not addressed by nursing. Although interview with the Rehab Manager (Manager #1) on 8/2/18 at 12:54 PM indicated that the Patient would receive ROM through repositioning, ROM to the upper and/or lower extremities was not documented by nursing. The facility policy for nursing process and plan of care identified that the plan of care is developed within 24 hours of admission and existing and identified problems, goals and interventions are evaluated once every 24 hours and updated as clinically relevant.

9. DPH Plan of Correction	Completion Date
• The East Pavilion (EP) 9-7 clinical Registered Nurses will receive reinforcement on the importance of including the problem of impaired mobility in the nursing plan of care with documentation of appropriate interventions.	January 31, 2019
• The expectations for impaired mobility documentation will be reviewed through EP 9-7 daily safety huddles for one week.	December 22, 2018
• To ensure daily assessment of a patients mobility needs, the provider progress note template will be standardized to include mobility assessment and intervention.	March 31, 2019
• Monitoring Plan: o Five medical records per month for three months will be audited to ensure that EP 9-7 patients with impaired mobility have an appropriate nursing plan of care documented that addresses impaired mobility interventions, utilizing daily mobility rounds. Beginning : February 1, 2019	
• The Patient Services Manager of EP 9-7 has been designated to oversee the reinforcement and monitoring of the corrective action plan.	April 30, 2019

10. *Based on clinical record review, review of hospital documentation and interviews for 2 of 4 patients who had dental and/or surgical procedures (Patients #29 and #30) the hospital failed to ensure that the patient's did not sustain burns during the procedures. The findings include:

a. Patient #29 was admitted to the dental department on 10/20/17 for a root canal. During the procedure, the area was irrigated with sodium hypochlorite (sterilizing agent) which was standard practice. At the time of irrigation the patient complained of pain. It was identified that the tooth had been perforated during the reaming process and as a result, the sodium hypochlorite leaked through the perforation and came in contact with the patient's gum tissue causing a chemical burn. Interview with Dentist #1 (Program Director) on 7/10/18 at 2:15 PM identified that this is a known complication of a root canal procedure and that sodium hypochlorite contact with tissue is caustic. The patient experienced pain and face swelling and was referred to a specialist to complete the root canal. Subsequent to this incident, the concentration of the sodium hypochlorite was changed to decrease the caustic nature of the irregant.

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10a. DPH Plan of Correction	Completion Date
• The High Reliability Organization (HRO) CHAMP behavior to Practice and accept a questioning attitude was incorporated into the Universal Protocol-Endodontic Procedures standard operating procedure (SOP) for the Dental Department. A pause will occur immediately prior to irrigation of canal of each tooth to Verify and Validate the file is in the canal via radiograph.	December 21, 2017
• This event was shared at the morning huddle in the Adult Dental Department clinic to reinforce the appropriate indications for conducting a pause prior to irrigation to Verify and Validate the file is in the canal via radiograph prior to irrigation.	November 30, 2017
• Residents, Attendings, and staff were re-educated on the Universal Protocol-Endodontic Procedures SOP for the Dental Department incorporating the HRO CHAMP behaviors with the emphasis on Validate and Verify during the pause that the file is in the canal via radiograph prior to irrigation.	December 5, 2017
• This event was shared at the Dental Grand Rounds emphasizing the need to reinforce the appropriate indications for conducting CHAMP behavior to Practice and accept a questioning attitude into Universal Protocol-Endodontic Procedures SOP for the Dental Department including a pause prior to irrigation of the canal of each tooth to Verify and Validate that the file is in the canal via radiograph.	December 14, 2017
• The attending dentist was counseled on the Universal Protocol-Endodontic Procedures SOP for the Dental Department and reeducated on the use of irrigating solutions.	January 5, 2018
• Five, or all if less than five, medical records per week were audited for three months to verify adherence to the revised Universal Protocol-Endodontic Procedure SOP for the Dental Department for patients undergoing a root canal, with 100% compliance.	March 30, 2018
• The Interim Program Director for the Adult Dental General Practice Residency Program was designated to oversee the monitoring of these correction actions.	

b. Patient #30 was admitted on 4/3/17 with a diagnosis of hepatocellular carcinoma and underwent a laparoscopic liver ablation and biopsy. For the procedure an ablation device was used with two thermal grounding pads, one on each of the patient's inner thighs. Additionally, a Bair Hugger machine was used to cover and warm the patient per usual practice. During the procedure, the thermal grounding pad alarm alerted that the pads were overheating. At that time the Bair Hugger was turned to cooling mode and the remainder of the procedure was completed. Following the removal of the thermal grounding pads Patient #30 was noted with a 6cm x 4cm skin tear to the left inner thigh and a 10cm x 3 cm skin blister to the right inner thigh. Subsequent to the procedure, Patient #30 was diagnosed with a 3rd degree burn to the left thigh that included necrotic tissue with full thickness tissue loss in two areas requiring wound debridement. The 3rd degree burn was noted to be healed on 6/26/18.

Interview with MD #37 on 8/15/18 at 7:00 AM identified that he had performed hundreds of these procedures and this was the only case where a patient sustained a burn from the thermal grounding

pad. MD #37 identified that all staff who were part of the surgical team had had previous training in the use of the equipment. Subsequent to the incident, staff received additional education on the use of the equipment and that the Bair Hugger is to be placed below the grounding pads.

Interview with the Patient Safety Coordinator on 7/10/18 at 12:25 PM identified that when the thermal grounding pads alarmed the Bair Hugger was set on cool and the alarm stopped. When the grounding pads were removed following the procedure, the patient's left thigh was red and thought to have been a skin tear as the pads are very sticky and had skin tissue on it. Also, it is not uncommon for skin to be red when grounding pads are removed. Following this incident, all equipment was checked and no issues were identified. The likely cause of the burn was using the Bair Hugger over the grounding pads.

10b.	DPH Plan of Correction	Completion Date
•	Clinical Engineering evaluated the performance of the ablation device used during the procedure and determined it to be functioning appropriately.	August 5, 2017
•	A multi-disciplinary team was convened to develop a process that serves as a guide in the identification, communication, and education of peri-operative staff regarding newly stocked equipment and supplies.	September 1, 2017
•	Peri-operative Services instituted a process to identify high-risk, low frequency equipment, beginning with the ablation unit, and create competencies that incorporate high reliability principles such as; ask an expert and validate and verify.	October 1, 2017
•	Leadership training was provided to enhance the use of high reliability principles and tools for the key team member roles of Unit Leaders and Specialty Coordinator.	September 20, 2017
•	The event was shared via newsletter with the peri-operative staff as a safety story and include discussion of the specific CHAMP behaviors; attention to detail, validate and verify and clear communication.	September 15, 2017
•	The Executive Nursing Director of Peri-operative Services was designated to oversee the monitoring of these corrective actions.	

The following is a violation of the Regulation of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (c) Medical Staff (2) and/or (4) (A) and/or (d) Medical records (3) and/or (e) Nursing service (1) and/or (f) Diagnostic and therapeutic facilities and/or (i) General (6).

11. *Based on medical record review, review of facility policies, review of facility documentation and interviews for two of 16 patients reviewed for surgical services (Patient #57, #31), the facility failed to ensure that surgical instruments were not retained and/or staff were competent to remove a retained surgical instrument and/or ensure the safety of the patient intra-operatively and/or that the clinical record was accurate. The findings include:
    a. Patient #57 was admitted to the hospital on 3/14/18 with a 20 millimeter pelvic mass and scheduled for a robotic hysterectomy, bilateral salpingo-oopherectomy and resection of the pelvic mass. Review of the operative report dated 3/14/18 authored by MD #45 (Surgeon) indicated a RUMI uterine manipulator was placed in the cervix. The operative report and intraoperative documentation indicated all instrument and sponge counts were correct twice and MD #45 was present and scrubbed for the entire duration of the procedure.

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Review of RN #22's nurse's note dated 3/14/18 at 9:39 PM identified that the patient was received in the post anesthesia care unit (PACU) with stable vital signs, pain was relieved with fentanyl, intravenous (IV) Tylenol, and repositioning/knee elevation.

Record review and interview with RN #22 on 8/20/18 at 2:55 PM stated that when she turned and repositioned the patient, she observed plastic tubing, approximately 6-8 inches in length protruding from the patient's genitalia, she called and spoke with Resident #3, who requested that she remove the occluder that was utilized during surgery. RN #22 stated she had never removed an occluder balloon (part of the uterine manipulator) before and had no formal training for such. Review of the record failed to reflect that RN #22 documented that the occluder balloon was retained, her conversation with Resident #3, the removal of the occluder balloon and/or the patient's response to the removal of the retained surgical instrument.

Interview with Surgical Scrub Technician #1 on 9/6/18 at 10:45 AM stated on 3/14/18, she recalled completing the initial count prior to the start of the case with the Circulating Nurse (RN #24) and her routine is that she always counts the occluder balloon and would tell the nurse who documents this information. Surgical Scrub Technician #1 stated she gave report to Surgical Scrub Technician #2 at 4:20 PM then left the case.

Interview with Surgical Scrub Technician #2 on 8/31/18 at 12:10 PM stated when she entered the case on 3/14/18 at 4:20 PM, Resident #2 was in the process of doing the vaginal closure and that she did the final count with the Circulating Nurse (RN #24) who informed Resident #2 that counts were correct times two. Surgical Scrub Technician #2 stated the circulating nurse documents the counts and informs the surgeon of the count.

RN #24 was not available for interview.

During an interview on 9/6/18 at 8:25 AM, MD #45 indicated the RUMI uterine manipulator was placed by him in the beginning of the case. Once the surgery was completed, MD #45 stated MD #55 (Fellow) was in charge of the remainder of the surgery as he moved to his next case. MD #45 identified that he received a call that the occluder balloon was not removed before the patient left the operating room and removed by the PACU nurse post-operatively at the direction of Resident #3. MD #45 further stated that he thought the occluder balloon was part of the counts, however, was not, and that he expected this device to be removed intra-operatively.

Interview with Resident #2 on 9/24/18 at 3:30 PM identified that he should have removed the patient's Foley catheter and occluder balloon at the end of the case but was addressing a concern that the clamp that held the stirrup on the table came off causing the patient's leg to fall off the table.

Interview with the Operating Room Manager on 8/20/18 at 1:30 PM identified that during the period of time in which this event occurred (3/18), the OR staff were not counting

vaginally inserted items. Subsequent to this event, the count worksheet was amended to include such instruments and all staff were educated.

Review of the Prevention of Retained Surgical Items (RSI) policy indicated instruments include all surgical tools or devices designed to perform a specific function. The policy indicated all counts after the initial count will start at the surgical field, move to the mayo stand, to the back table and off the field. The count sheet in the kit will be used to perform the initial instrument count. If there is no count sheet, total the instruments on the field and record the total on the count sheet/white board.

The facility policy for prevention of retained surgical items identified that any item not identified as a sponge, sharp or instrument that are opened onto the sterile field are accounted for during all procedures. The policy further directed that counts must be done visually and audibly by the scrub person and RN circulator and in part, prior to wound closure.

11a.	DPH Plan of Correction	Completion Date
•	This event was shared throughout Peri-operative Services to demonstrate how CHAMP behaviors such as critical thinking and clear communication can be used to mitigate further similar events.	May 11, 2018
•	To prompt critical thinking and HRO behaviors, the count worksheet was optimized to include a specified location for the recording of miscellaneous surgically placed items, including disposables, which are placed into a cavity during surgical cases.	May 18, 2018
•	A team consisting of Peri-operative leadership and front-line staff (i.e., Register Nurses and Surgical Technicians) developed a formal communication hand-off process which will be utilized during surgical cases and include the review of miscellaneous items which are placed in a cavity.	July 2, 2018
•	The Executive Nursing Director of Peri-operative Services has been designated to oversee the monitoring of these corrective actions.	
•	All York Street campus Post-Operative Care Unit Registered Nurses were educated on what to do in the event an occluder balloon is found in place post-operatively.	December 6, 2018
•	Education on occluder balloon retention and the process for resolution was communicated at huddles and staff meetings.	December 6, 2018
•	Individual coaching and re-education with the Registered Nurse regarding documentation standards has been completed.	December 6, 2018
•	The Patient Service Manager of the York Street campus Post-Operative Care Unit was designated to oversee the monitoring of these corrective actions.	

b. Review of Patient #57's operative record dated 3/14/18 identified that the surgical procedure started at 3:38 PM and Scrub Technician #1 was present for the case from 2:32 PM through 4:47 PM. Review of the record identified that Scrub Technician and RN #24 performed the initial and first count. Interview with Surgical Technician #1 on 9/6/18 at 10:45 AM stated she recalled competing the initial count prior to the start of the case with the Circulating Nurse (RN #24) and was not present for the First closing count. Interview with the OR Manager on 9/6/18 at 11AM

stated that the record was inaccurate in that RN #24 may have chosen the wrong Scrub Technician's name in the pull down section of the electronic medical record.

11b. DPH Plan of Correction	Completion Date
• All North Pavilion Operating Room Registered Nurses will be re-educated on proper intra-operative documentation of final counts, including accurate documentation of staff involved. • Monitoring Plan: o Five medical records per week for four weeks will be audited for accurate documentation of staff involved in final counts. Beginning : January 7, 2019 • The Patient Services Manager of North Pavilion Operating Room has been designated to oversee the monitoring of these corrective actions.	January 4, 2019 February 1, 2019

c. Review of Patient #57's operative report dated 3/14/18 identified that during mobilization of the patient from the operating room table to the stretcher, the stirrup that held the patient's leg in position during surgery, came unhinged. The patient did not appear to be injured, but an x-ray was taken and an orthopedic consult was called. Review of the pelvic x-ray report dated 3/14/18 identified no new fracture or dislocation was noted.

Review of facility documentation reflected that "upon completion of the case (3/14/18), the patient was in the lithotomy position, the right leg was repositioned for it was not positioned properly (lower than the left), the right leg fell with the stirrup still attached to it after the Resident let go after repositioning". Review of this incident with the OR Manager on 8/20/18 at 1:30 PM stated the stirrup was connected to the OR bed frame with a lug and subsequent to the incident, the lug was replaced. The Manager stated a work order was not requested. The hospital failed to ensure that human error was not ruled out as part of the investigation including but not limited to ensuring the patient's leg was properly placed in the stirrup and/or during position changes intra-operatively.

11c. DPH Plan of Correction	Completion Date
• North Pavilion Operating Room staff, gynecology surgeons and residents who utilize yellow fin stirrups for patient positioning will be re-educated on the nced to verify proper securement. • Monitoring Plan: o Observation audits on two gynecology cases per week for four weeks will be performed to verify that patients are properly secured in yellowfin stirrups. Beginning : January 7, 2019 • The Patient Services Manager of North Pavilion Operating Room has been designated to oversee the monitoring of these corrective actions.	January 4, 2019 February 1, 2019

d. Patient #31 was admitted to the hospital on 6/15/17 with hypertensive urgency, shortness of breath, and chest pain. Review of the record identified that the patient had a cardiac catheterization on 5/20/17 which noted moderate to severe aortic valve stenosis. The patient was evaluated by MD#56 (cardiac surgeon) with a plan for aortic valve replacement on 6/22/17.

Review of the operative report dated 6/22/17 identified that two (2) atrial wires were placed and the patient was in sinus rhythm. A nurse's note dated 6/22/17 at 7:55 PM identified that the patient arrived to the intensive care unit, 100% AV paced at 80 bpm via epicardial wires, wires disconnected by PA, underlying normal sinus rhythm 60s-70s and wires reconnected to pacemaker at backup rate of 45.DDD.

Review of the chest x-ray dated 6/23/17 noted interval placement of right apically terminating chest tube with resolution of right pneumothorax. Review of the clinical record dated 6/25/17 identified that the chest tube was removed at 12:10 PM.

Review of a nurse's note dated 6/26/17 at 2:40 AM noted that the patient's AV wires remain in place, surgical sites dry and intact, previous pleural chest tube dressing dry and intact. Review of the discharge nursing note dated 6/26/17 at 10:47 AM identified that the patient's epicardial wires were removed by the PA and the patient was discharged via wheel chair accompanied by RN. The record failed to note an assessment of the surgical sites by nursing staff prior to discharge.

Review of the discharge summary authored by PA #2 dated 6/26/17 at 11:09 AM indicated that the patient's right chest tube was removed on 6/26/17 with no residual pneumothorax on follow-up chest x-ray. The record failed to indicate that the atrial wire was removed prior to discharge and/or an assessment of the patient's surgical incisions.

Review of the clinical record with the Performance Improvement Manager and the Clinical Manager for cardiac/thoracic surgery, Physician Assistant (PA) #1 on 8/10/18 at 10:20 AM stated the record failed to indicate that PA #2 documented the removal of the pacer wires before discharge on 6/26/17 and during a post-operative visit on 6/30/17, MD #56 removed the temporary atrial pacing wire and one chest tube stitch.

Interview with MD #56 on 8/20/18 at 2:20 PM stated the atrial pacer wire should have been removed prior to discharge and believed it was overlooked because the patient had a dressing in place secondary to bleeding from the chest tube site.
PA #2 was unavailable for interview.

11d.	DPH Plan of Correction	Completion Date
•	The Cardiothoracic Advanced Practice Providers (APPs) will document whether thoracostomy/chest tubes and wire were removed or whether they were left in place and for what reason.	August 13, 2017
•	As a double-check, on the day of discharge, Cardiothoracic APPs or Registered Nurses will document an assessment of the surgical site(s).	August 13, 2017

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• Audits were conducted on five patients per week for three months to ensure documentation for appropriateness of wire/tube/line removal and for discharge note if any wire/tube/line had been left in place with 100% compliance. • The Patient Service Manager of the Cardiothoracic Intensive Care Unit was designated to oversee the monitoring of these corrective actions.	November 13, 2017

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12. Based on clinical record review and interview for 2 (P#5, P#8) of 4 patients reviewed for patients' rights the hospital failed to ensure the patients received high quality coordinated care and/or appropriate requested care and treatment. The findings include:

    a. Patient (P) #5, with a medical history of anxiety and amyotrophic lateral sclerosis (ALS) resulting in the inability to speak and eat resulting in a feeding tube for supplemental nutrition, presented to the Emergency Department (ED) on 12/6/17 at 8:47 AM from the outpatient neuromuscular clinic for a scheduled admission and elective tracheostomy placement on 12/7/17.

    According to an admission History and Physical (H&P) the plan of care was to admit P#5 to the Neurology stepdown unit.

    P #5 is evaluated by the Neurology Team at 9:54 AM and at 11:01 AM an order is written to admit P #5 to step down level of care. At 12:54 PM admission orders are entered and report is called from the ED to the unit at 1:26 PM however P#5 is not transferred to the unit until 12/7/17 at 12:49 AM (approximately 16 hours from arrival in ED). In addition at 12:54 PM an order is entered indicating that P #5 is to have nothing by mouth. P#5 is evaluated by nutrition services at 4:51 PM and the NPO order is verified at 5:57 PM and a tube feed diet is ordered at 6:04 PM and started (approximately 9 hours from arrival in ED).

    Hospital documentation of the review of P#5's Grievance investigation identified Medical Doctor (MD) #3 indicated medical record review identified no call was made to the ED from the outpatient neurology clinic to arrange an admission on 12/6/17 causing a lack of communication between the Neurology team and the ED. ED care was reviewed and seemed reasonable although P#5 waited 16 hours for admission from the ED to a hospital unit. A neurology note asked that P#5 remain NPO pending the decision regarding the time of surgery on 12/7/17 however the decision to resume tube feedings was not made until approximately 7PM. MD#3 indicated he/she appreciated P#5's frustration.

    During an interview with the Patient Grievance Coordinator on 7/24/18 at 12:27 PM he/she indicated in review of P#5's concerns areas for improvement were identified as clearer documentation and communication was need between Neurology and the ED staff to better

understand the plan of care. In addition ED staff was provided additional education on caring for a patient with ALS and patients with deficits in communication.

12a. DPH Plan of Correction	Completion Date
• Yale New Haven Hospital created a standard operating procedure to proactively address surges in patient activity within the hospital.	January 31, 2018
• A process for improved communication and documentation by referring neurology team for patients admitted through the Emergency Department has been implemented.	August 31, 2018
• Education was provided to the York Street Campus Adult Emergency Department nursing staff regarding patients with communication issues, ensuring call bells, rounding and awareness of patient communication needs.	May 31, 2018
• The YNHH Executive Director of Clinical Operations, Amyotrophic Lateral Sclerosis Clinic Director and the Patient Services Manager of the YSC AED were designated to oversee the monitoring of these corrective actions.	

b. P #8 was evaluated in the ED on 8/26/17 for evaluation of cholelithiasis. P #8 had diagnoses that included Diabetes Mellitus (DM) and was monitoring his/her blood sugar and administering insulin as needed at home.

A onetime blood sugar (BS) was ordered and checked on 8/26/17 at 6:14 PM in the ED with a result of 198 mg/dL (normal value 70-130 mg/dL). MD orders dated 8/27/17 indicated P#8 was to receive regular human Insulin every 6 hours on a sliding scale based on BS results.

A BS was ordered and checked at the request of P #8 in the ED on 8/27/17 at 1:00 AM with a result of 181 mg/dL. P #8 was admitted and underwent an MRI and was transferred to a patient care unit. Upon arriving on the patient care unit a BS was checked at 3:37 AM with a result of 171 mg/dL. In review of the medical record the medical record lacked evidence blood sugars had been checked after on 8/27/17 from 3:37 AM until 5:46 PM at which time the result as 286 mg/dL. Subsequent to an evaluation by MD #1 P #8 received insulin and his/her blood sugar was monitored.

During an interview with the Manager of Patient Relations on 7/11/18 at 11:40 AM he/she indicated P #8 had expressed concern on 8/27/17 that he/she had made several inquiries during the day asking RN #2 to check his/her blood sugar. P #8 indicated he/she was upset and anxious at the time because he/she was concerned if his/her blood sugar was not controlled P #8 would develop complications such as loss of eyesight. P #8 indicated RN #2 indicated he/she could not check his/her blood sugar without a physician's order.

During an interview with RN #2 on 7/26/18 at 10:00 AM RN #3 did not recall the circumstances in caring for P#8 however he/she indicated if a patient asked for a blood sugar checks RN #2 would check for a physician's order. If there was no order he/she would call the MD and ask for an order.

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During an interview with Assistant Patient Service Manager #1 on 7/24/18 at 2:00 PM he/she indicated the expectation would be if a DM patient came from the ED without BS monitoring orders the nurse should call the physician for orders. In this case RN #2 did not check P#8's blood sugar at P#8's request and/or call the physician for orders and he/she should have.

Hospital Patient Rights and Responsibilities Policy indicated the patient has the right to receive high quality coordinated care that is respectful and considerate and focused on the patient's individual needs. In addition the patient has the right to request care and treatment that is deemed medically necessary and appropriate within the hospitals capacity.

12b. DPH Plan of Correction	Completion Date
• The East Pavilion (EP) 6-5 Registered Nurses received in-service on the importance of requesting an order for blood glucose testing as needed for patients with Diabetes Mellitus.	August 30, 2018
• The Nursing Resource Operation Center Registered Nurse received reinforcement on the importance of requesting an order for blood glucose testing for patients with Diabetes Mellitus.	September 30, 2017
• The York Street campus Nursing Resource Operation Center Medical-Surgical Registered Nurses will receive reinforcement on the importance of requesting an order for blood glucose testing for patients with Diabetes Mellitus.	January 31, 2019
• Monitoring Plan: o Five medical records per month, or all if less than five will be audited for three months for EP 6-5 patients with Diabetes Mellitus for blood glucose testing orders on admission. Beginning : December 10, 2018	March 10, 2019
• The Patient Services Manager of EP 6-5 has been designated to oversee the monitoring of these corrective actions.	

The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (c) Medical Staff (4) and/or (d) Medical Records (2) and/or (e) Nursing Service (1), and/or (i) General (6).

13. Based on clinical record review, interview and policy review for 4 patients (Patients #24, #40, #43 and #44) the facility failed to ensure that the interdisciplinary treatment plan was reviewed, revised, updated and/or had input from all members of the ITP. The findings include the following:
    a. Review of Patient #24's clinical record indicated that the patient was admitted on 9/13/17 with a history of PTSD, depression presented with suicidal ideation. The physician note dated 9/26/17 indicated that Patient #24 disclosed to staff that he/she had been sexually touching another peer. The plan of care note dated 9/26/17 indicated that staff were informed by the physician that the patient alleged he/she engaged in inappropriate physical contact with roommate. The note indicated that the patient was placed in a single room and single seat within the milieu. Patient #24 was upset to be placed on single seat plan and was moved to a private room. Review of the interdisciplinary treatment plan (ITP) dated 9/21/17 failed to reflect that the ITP had been updated

after the incident and/or prior to discharge on 10/19/18. Interview with RN # 16 on 7/25/18 at 9:00 AM indicated that the ITP should be updated every seven days or with a change of condition. Review of the policy indicated treatment is planned and delivered in an interdisciplinary and collaborative manner. The ITP is initiated within 24 hours and completed within 72 hours of admission by the treatment team, it is reflective of initial and ongoing biophysical assessment of the patients.

In addition review of the ITP dated 9/21/17 failed to identify the names of the people involved in the creation of the ITP. The ITP listed the disciplines involved only. Interview with PSM # 3 on 7/25/18 at 9:30 AM indicated that there is a glitch in the computer system and that staff have to manually enter the names of staff involved. Interview with MD #33 on 8/1/18 at 10:00 AM indicated that the physician does not document on the ITP. MD #33 indicated that staff discuss issues at team meetings.

b. Patient #40 admitted 9/20/17, the patient had a history of trauma, major depressive disorder and self-injurious behaviors being admitted for worsening depression with active suicidal ideation with a plan. Review of the treatment plan indicated that the patient's active problem was suicide ideation. Review of the physician's note dated 9/26/17 at 10:41 PM indicated that he met with the patient after hearing that he/she had sexual interaction with Patient #24. The note indicated that the patient was visibly shaken by the discussing this topic and appeared to have triggered from prior trauma. The note indicated that staff would plan to keep Patients #24 and 40 apart during groups, outside time and school. Review of the ITP dated 9/20/17 failed to reflect that the ITP was updated following this event and/or that the ITP was updated/revised prior to discharge on 9/28/17.

13 a,b. **DPH Plan of Correction**	**Completion Date**
• The Yale New Haven Hospital Interdisciplinary Treatment Plan (ITP) for the Psychiatric Department was optimized to include documentation of the names of people involved in the creation of the ITP.	October 23, 2018
• Children's Psychiatric Inpatient Services (CPIS) registered Nurses (RNs) will be educated regarding the new ITP functionality in the electronic medical record and timely documentation of any clinical event requiring an ITP update.	January 30, 2019
• CPIS medical staff and RNs will be educated on reviewing, revising, updating and identifying all members of the treatment team in the ITP.	January 30, 2019
• Monitoring Plan: o Four CPIS medical records will be audited weekly for compliance with documentation of ITP, timely reviewing of ITP by MD and involvement of the treatment team during ITP review, for two months. Beginning: January 31, 2019	March 29, 2019
The Patient Service Manager of CPIS has been designated to oversee the monitoring of these corrective actions.	

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c. Patient #43 was admitted on 7/19/18 with new onset psychosis. Review of the clinical record indicated that the ITP was completed on 7/20/18 and updated on 7/26/18 and 7/27/18 however the ITP failed to reflect the involvement of the physician in the process, failing to make the plan interdisciplinary.

d. Patient #44 was admitted on 7/21/18 with homicidal ideation. Review of the record indicated that an ITP was completed on7/22/18 however the ITP failed to reflect the involvement of the physician in the process failing to make the plan interdisciplinary.

13 c,d. DPH Plan of Correction	Completion Date
• The Yale New Haven Hospital Interdisciplinary Treatment Plan (ITP) for the Psychiatric Department was optimized to reflect involvement of the physician in the ITP. • Liberty Village 2 (LV2) physicians will be educated on the ITP optimization and need to review and sign ITPs. • Monitoring Plan: o Five LV2 ITPs will be audited weekly to ensure physician signature for two months. Beginning: January 14, 2019 The Patient Service Manager of Adolescent Unit (LV2) has been designated to oversee the monitoring of these corrective actions.	October 23, 2018 January 11, 2019 March 14, 2019

The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (d) Medical Records (2) and/or (e) Nursing Service (1), and/or (i) General (6).

14. Based on clinical record review, interview and policy review the facility failed to ensure that for 1 of 2 patients (Patient #38) that a safe discharge plan was in place. The findings include the following:

a. Patient #38 presented to the ED via ambulance on 7/24/17 at 9:47 AM from a Skilled Nursing Facility (SNF). The patient complained of a large cyst under his/her breast, with complaints of an 8/10 pain. The note at 12:57 PM indicated that the patient was to be admitted. The physician note indicated that the patient had a 2 cm by 2 cm area under the right breast. The physician assistant note dated 7/24/17 at 11:42 M indicated that after the initial decision to admit the patient the patient became irritate because he/she was not receiving opioid pain medication. The patient indicated that he/she did not want to be admitted. The nurse's note dated 7/24/17 at 1:13 PM indicated that the patient was screaming at staff stating, "I just want you all to leave me alone, just get me discharged, I'm in pain, and you haven't even given me antibiotics yet". The note indicated that the patient refused a bedside US, lab and oral pain medication. The note dated 7/24/17 at 1:22 PM indicated that clindamycin and Ibuprofen were administered. Patient was given discharge instructions by RN. Patient screaming "I'll find my way out", not wanting to stay for vitals or provider instruction.

The PA note dated 7/24/17 at 1:13 PM indicated that several hours after the patient had left the SNF called looking for the patient. The noted indicated that the PA, MD, ED Nurse Manager and RN discussed the case and reaffirmed that the patient had the mental capacity to make decisions.

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The ED admission dated 7/25/17 at 10:27 AM indicated that the patient returned to the ED. The note indicated that the patient had been seen the previous day and was discharged to the street instead of being sent to Leeway.

Review of the facility policy related to Discharge Planning indicated that the physician/RN will assess discharge disposition and coordinate travel if appropriate, facilitate preparation for a safe discharge and participate in information exchange with post discharge facility when appropriate. Review of the Patient Rights policy indicated that the patient has the right to receive high quality coordinated care that is respectful and considerate.

14 a.	DPH Plan of Correction	Completion Date
	• It was identified that there is an opportunity to communicate with this Skilled Nursing Facility (SNF) when any of their residents leave Yale New Haven Hospital (YNHH) York Street Campus (YSC) Emergency Department (ED) against medical advice (AMA). The provider or designee will ensure attempts are made to contact the facility.	
	• The YSC ED's Medical Director will discuss this expectation with YSC ED faculty and residents at the faculty meeting on January 17, 2019	January 18, 2019
	• YNHH YSC ED's Clinical Manager of Advanced Practice Practitioners (APP) will notify all ED APP via email with read receipt by January 17, 2019, as well as discuss this expectation with ED APP at the APP staff meeting on February 7, 2019.	February 8, 2019
	• Monitoring Plan: All patients from a SNF that leave YSC ED AMA will be audited monthly for two months, to ensure the SNF was informed of patient's disposition. Beginning: January 21, 2019	March 18, 2019
	The Patient Service Manager of YSC ED has been designated to oversee the monitoring of these corrective actions.	

The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (d) Medical Records (2) and/or (e) Nursing Service (1), and/or (i) General (6).

15. Based on the clinical record review, interview and policy the facility failed to ensure that for 1 patient (Patient #39) the patient's level of pain was assessed and/or the patient's level of pain was addressed in a timely manner. The findings include the following:

a. Patient #39 presented on 7/5/17 to 11:58 AM for permcath removal, refusing to start dialysis because of pain and anxiety. The patient had complaints of chronic generalized pain, a 9 on a scale of 0-10 at 12:00 PM. The physician note indicated that the patient was to be admitted for pain management, electrolyte evaluation and a psychiatric evaluation. Review of the ED record with the ED Manager on 8/20/18 at 10:00 AM indicated that Oxycodone 1 tablet was administered at 3:36 PM. The record failed to reflect the rationale for not addressing the patient's

level of pain initially. The record failed to reflect a pain reassessment prior to the administration of the medication. Review of Patient #39's clinical record indicated that at 4:37 PM the patient had a pain level of 9, however the record failed to reflect that the patient's pain level was addressed at that time.

Review of Patient #39's clinical record indicated that MD # 25 directed Oxycodone 10 mg every four hours for moderate pain (4-6). The clinical record indicated that on 7/5/17 at 5:00 PM the patient had a pain level of 10 that was not addressed. The record indicated that the patient received 10 mg of Oxycodone at approximately 7:00 PM, even though the stated pain level was outside the parameters ordered. The patient had a pain assessment of 10 at 11:07 PM and Oxycodone 10 mg was administered, the patient was reassessed for efficacy at 12:00 AM. The facility failed to ensure that the physician was notified of the patient's level of pain to comprehensively address the pain level of a 10.

Although review of the clinical record with the Nurse Manager on 8/20/18 at 10:15 AM indicated the patient received Oxycodone 10 mg on 7/6/17 at 5:21 AM, no further pain assessments were completed after the 12:00 AM assessment on 7/6/17 through discharge at 4:24 PM on 7/6/17.

15 a.	DPH Plan of Correction	Completion Date
•	Sister Louise Anthony 3 (SLA3) Clinical Registered Nurses will receive reinforcement on the importance of pain assessment, pain interventions and pain reassessment along with appropriate documentation in the electronic medical record.	January 31, 2019
•	SLA3 Clinical Registered Nurses will receive reinforcement on the importance of administering pain medications based on the patient's stated pain level and in correlation with the medication order.	January 31, 2019
•	SLA3 Clinical Registered Nurses will receive reinforcement on the importance of notifying the provider if the patient's pain is not well-controlled with the ordered medication to adjust interventions for better pain control.	January 31, 2019
•	Monitoring Plan: o Four records per week for eight weeks will be audited to ensure pain assessment, interventions and reassessment are completed and documented. Beginning: February 1, 2019	March 31, 2019
•	The Patient Services Manager of SLA3 has been designated to oversee the monitoring of these corrective action plans.	
•	YNHH developed an Electronic Medical Record (EMR) Emergency Services documentation guideline that specifically includes pain assessments, interventions and justification if no intervention was provided. The ED clinical registered nurses will be educated to the guideline.	January 4, 2019

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• Monitoring Plan:
  • Ten medical records per month for three months in YNHH SRC ED will be reviewed for documentation of pain assessments, interventions and justification if no intervention was provided.
  Beginning: January 7, 2019
• The SRC ED Patient Service Manger has been designated to oversee the monitoring of these corrective actions.
	April 5, 2019

The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (a) Physical Plant (4) and/or (i) General (6).

16. Based on tour the facility failed to ensure that a private sanitary environment was available to all patients on the children's psychiatric unit. The findings include the following:
    a. Tour of the children's psychiatric unit on 8/1/18 at 9:15 AM identified that the privacy curtains were not present throughout the unit in the semiprivate patient rooms, not allowing patient privacy while changing and/or sleeping. Interview with staff indicated that the curtains were removed because patients would pull them down and the facility would have to put the curtains back in place.
    b. Tour of the children's psychiatric on 8/1/18 at 9:15 AM identified that the floor in the common area was discolored and peeling.

16 a. DPH Plan of Correction	Completion Date

• Tracks, hooks, and temporary curtains will be added to all semiprivate patient rooms, between beds on Liberty Village 2 (LV2) to provide privacy.
• Permanent curtains will be installed on LV2 to provide privacy.
• LV2 common area floor will be stripped and recoated.
• Monitoring Plan:
  o All semi private rooms will be audited every other week to ensure privacy curtains are installed on LV2, for two months.
  Beginning : February 6, 2019
  o The common area floor will be audited every other week to ensure there is no discoloring or peeling on LV2, for two months.
  Beginning : February 6, 2019
• The Patient Service Manager of Adolescent Unit (LV2) has been designated to oversee the monitoring of these corrective actions.
	February 1, 2019
	March 1, 2019
	February 4, 2019
	
	March 20, 2019
	
	March 20, 2019

The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (d) Medical Records (2) and/or(e) Nursing Service (1) and/or (i) General (6).

17. Based on clinical record review, policy review and interview for 1 of 3 patients (Patient #4) the facility failed to ensure that CIWA monitoring was completed. The findings include the following: a.

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Patient #4 was admitted on 4/14/18 with a recent fall, depression, anxiety disorder, panic attacks and a history of benzodiazepine abuse on methadone. The H&P indicated that the patient stated that he/she obtained Xanax illicitly for depression.

Review of the 4/15/17 Psychiatric consult indicated that the patient endorsed depression and positive suicidal ideation in the ED. Patient reporting taking 2 mg of Xanax daily. Review of the physician's orders dated 4/16/18 at 11:10 AM directed CIWA monitoring to be completed three times a day. Review of the clinical record by the Quality representative indicated that the CIWA monitoring was completed on 4/17/18 at 10:00 PM and 4/18/18 at 6:00 AM. The facility failed to ensure that the monitoring was completed as directed.

17a	**DPH Plan of Correction**	**Completion Date**
	• The expectations for Clinical Institute Withdrawal Assessment (CIWA) monitoring and documentation was reviewed through East Pavilion (EP) 6-7 daily safety huddles for one week.	December 29, 2018
	• The EP 6-7 Clinical Registered Nurses will receive reinforcement on the importance of monitoring and documenting CIWA as ordered.	February 4, 2019

	• Monitoring Plan:
	  • Five medical records per month for three months will be audited to ensure that EP 6-7 patients with CIWA orders are monitored and receive corresponding documentation in the medical record.
	  Beginning: February 5, 2019
		April 30, 2019

	• The Patient Services Manager of EP 6-7 has been designated to oversee the monitoring of these corrective action plans.	